Cholestech GDX™

# System Procedure Manual

CHOLESTECH

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# *Foreword*

## Procedure Manual Overview

This Procedure manual has been designed to instruct Cholestech GDX users in how to comply with good laboratory practices and assist in complying with applicable regulations. The Cholestech GDX System Procedure Manual covers:

- Setup and Maintenance: Procedure to properly run an optics check and record the values for the Cholestech GDX System. In addition, the section provides specific information about recording laboratory environment conditions.
- Specimen Collection and Handling: General procedures applicable to obtaining a suitable specimen and running a test on the Cholestech GDX System.
- Quality Control: Discusses laboratory activities designed to ensure that each test system is working properly and that the test results satisfy quality standards.
- Testing Procedures: A test procedure that covers the Cholestech GDX.
- Safety: Allows you to file your safety guidelines as recommended by OSHA.
- Training: A checklist as a guideline to train personnel on the Cholestech GDX System.
- Material Safety Data Sheets: A copy of Cholestech Corporation's MSDS for the Cholestech GDX test cartridges, controls and Optics Check Cartridge. You can add MSDSs as required.
- Proficiency Testing Guidance: Discusses the importance of proficiency testing, how testing is performed and lists agencies offering proficiency testing.
- Master Forms: Master forms are provided for you to copy and use as needed.

An icon (a letter within a shape) will appear at the beginning of each section. These icons indicate:

The information in the following section is "For Information Only."

The information in the following section is "Recommended" by the manufacturer.

The information in the following section is recommended to comply with OSHA and CLIA '88 Moderately Complex Laboratory Regulations, as well as regulations that apply to users in certain states.

If you need assistance using the manual, please contact Cholestech Technical Service at 800-733-0404.

**Please note:** The following procedures are outlined as a guide, not a substitute for complying with state or federal regulations relevant to your site. Cholestech Corporation does not guarantee that following this guide will result in certification or meeting state or federal regulations. For further information regarding regulations, please refer to your state or federal agencies.

# *Introduction*

## Overview of a Quality Assurance Program

Quality assurance (QA) is a comprehensive set of policies, procedures and practices necessary to ensure the quality of laboratory tests. Its purpose is to ensure that over the long term, the laboratory provides reliable data that accurately reflect the patient's status. Quality assurance in a point-of-care laboratory covers nine basic areas:

1. Policies and standards that govern the laboratory cover elements that affect test quality before (patient preparation, sample collection, etc.), during and after (data transcription errors, etc.) the testing process.

2. Training: All personnel conducting tests should be properly trained and their training documented.

3. Safety policies should be adhered to and a safe working environment provided.

4. Procedure manuals should contain operating protocols that are complete, up to date and available to laboratory personnel.

5. Record keeping: All aspects of the quality assurance program should be documented in writing as appropriate.

6. Quality control may include initial verification of the test method, routine testing of quality control materials and a written procedure for responding to "out of control" test results. All quality control procedures and follow-up actions should be documented.

7. Participation in proficiency testing program is optional for CLIA-waived tests. Proficiency testing may be performed and documented when required by local or state regulations.

8. Laboratory inspections may be conducted by the appropriate organization to assess quality assurance and suggest possible improvements.

### A successful QA program assures that:

1. Policies and procedures are established in writing and followed by all personnel involved in the testing process.

2. The test system performs properly at the time patient results are produced.

3. Written records are available to demonstrate that uniform procedures have been established and are followed.

The material in this procedure manual can assist in assuring that the quality of test results in the laboratory or at a testing site are satisfactory over time.

# 1.0 Setup and Maintenance

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# Setup and Maintenance

## 1.1 Introduction

This section contains the procedure to properly run an optics check and specific information about proper maintenance. A sample copy of each form referred to is included in the Master Forms section of this manual.

## 1.2 Environmental Requirements

Use your Cholestech GDX System in a location that has:

- Temperature 63–86ºF (17–30ºC)
- A stable work surface
- No direct heat (oven or room heater)
- No bright light (sunlight or a spotlight)

It is important to prevent dust and dirt from getting into the Analyzer. Keep the Analyzer covered when not in use.

If the temperature or light requirements are not acceptable, the Analyzer will shut down until they are met.

## 1.3 Optics Check Cartridge

The Optics Check Cartridge is reusable. It is designed to check that the Analyzer is working correctly. The cartridge contains a resin with a dye that acts like your blood sample. The Analyzer will automatically recognize when an Optics Check Cartridge is being used.

The Optics Check Cartridge should be run every day the Cholestech GDX Analyzer is used. If you are concerned that your test result is incorrect, also run the quality control material.

## 1.4 Optics Check Cartridge Test Procedure

Do not use a Cholestech GDX Optics Cartridge that is expired, damaged or altered in any way.

1. Plug in the Analyzer and allow to warm up.
2. Place the cartridge in the Analyzer when the Insert Cartridge icon flashes.
   - "C 0" appears on the display and the Hourglass icon is displayed.
   - The Rotate Cartridge icon is displayed. The Analyzer will beep and the light at Position 1 will flash.
3. Turn the cartridge to Position 1.
   - "C 1" and the Hourglass icon will show on the display.
   - The Rotate Cartridge icon will be displayed. The Analyzer will beep and the light at Position 2 will flash.
4. Turn the cartridge to Position 2.
   - "C 2" and the Hourglass icon will show on the display.
   - The Rotate Cartridge icon will be displayed. The Analyzer will beep and the light at Position 3 will flash.



I For Information Only R Recommended O Optional Information

5. Turn the cartridge to Position 3.
   - "[ ]" and the Hourglass icon will show on the display.
   - The Rotate Cartridge icon will be displayed.
6. Turn the cartridge to Position 0.
   - The Remove and Cartridge icons will be displayed.
7. Remove the cartridge.
   - The Analyzer will display the result: e.g., C 10.7%
8. Record the results in the Cholestech GDX A1C Result Log each day.

**Note: "[" stands for Optics Check Cartridge.**

9. Press the "enter" button to clear the Optics Check Cartridge result.

### Storage

Always store the Optics Check Cartridge at room temperature in its box. This will help to protect it from damage such as scratches, which may affect the result.

The cartridge must not be left in direct sunlight for long periods while not in use.

The Optics Check Cartridge must be stored at relative humidity of less than 60%.

### Results

The results displayed on the Analyzer at the end of Optics Check Cartridge test must be in the range on the cartridge label.

If the result does not fall within the range displayed, do the following:

- Clean the clear plastic surface of the cartridge with a soft, lint-free cloth. Do this on the inside and outside of the cartridge. Follow the test from point 2.
- If the result is still not in the correct range, restart the Analyzer by unplugging and replugging it and run the Optics Check Cartridge.
- If the result is still not in range, contact Cholestech Technical Service.
- If the cartridge is physically scratched, dirty or damaged, replace the cartridge with a new Optics Check Cartridge.

**Warning: For *In Vitro* Diagnostic Use**

When the test is finished, the Optics Check Cartridge should be returned to its protective packaging for storage. Do not use the Optics Check Cartridge if it has been stored incorrectly and is scratched or damaged in any way.

For technical help and troubleshooting, please refer to the Cholestech GDX A1C Test Cartridge package insert and the User Manual. If technical help is required, please contact Cholestech Technical Service at 800-733-0404.

## 1.5 Shelf Life Stability

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Optics Check Cartridges have a shelf life date. The expiration date is printed on the top of the Optics Check Cartridge. Do not use the Optics Check Cartridge after the end of the shelf life date.

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## 1.6 Laboratory Temperature Records

Forms are included in this manual (see *Master Forms* section) to record the temperature of the laboratory room and refrigerator. Each form is designed for a daily record to be recorded. There is space for the site identification, the acceptable temperature range and daily temperature records. Record the temperature and your initials in the allocated spaces.

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## 1.7 Instrument History Record

Proper, continuing care for a laboratory instrument has primary importance, as it minimizes breakdowns and ensures proper results.

The **Instrument History Record** allows lab personnel to communicate effectively with Cholestech Technical Service. You should have a record for your Cholestech GDX System as well as records for any other instruments in the lab (refer to the *Master Forms* section of this manual).

Several general guidelines are helpful in ensuring satisfactory preventive maintenance:

- Select one person to have principal responsibility for a given instrument.
- Make sure that this person is familiar with the user manual, the procedure manual and the package insert for each test system.
- Perform all required preventive maintenance called for in the Cholestech GDX Analyzer User Manual.
- Keep all spare parts recommended by the manufacturer on hand.

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## 1.8 Cholestech GDX System Initial Setup

The **Initial Setup Checklist** is provided to assure that all of the environmental conditions are met and that the Cholestech GDX System runs properly during the initial setup in the laboratory. Refer to the *Master Forms* section of this manual.

The **Instrument History Record** can be used to record any service performed on the Cholestech GDX System or other instruments in your laboratory. Both forms can be found in the *Master Forms* section of this manual.

Cholestech Corporation will provide technical support to each Cholestech GDX System user. Any questions regarding the operation of the Cholestech GDX System may be directed to:

Cholestech Corporation
Technical Service Department
3347 Investment Blvd.
Hayward, CA 94545 U.S.A.
Tel 800 733.0404
Fax 510 732.7227
**www.cholestech.com**
**techservice@cholestech.com**

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## 1.9 Maintenance and Cleaning of the Cholestech GDX System

No maintenance is required other than routine cleaning when necessary.

- Clean the outside of the Cholestech GDX Analyzer case with a clean, damp, nonabrasive cloth. Most spills and stains will be removed with water or a mild detergent. A solution of 70% isopropyl alcohol, or 5% bleach, or any nonstaining, commercially available disinfectant are all appropriate cleaning agents. Do not immerse the instrument in water or other cleaning fluid. Do not use any abrasive cleanser.

You can record maintenance and cleaning performed on the Cholestech GDX System and other instruments in your laboratory on the Equipment Maintenance/Cleaning Log in the *Master Forms* section of this manual.

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## 1.10 Course of Action If System Becomes Inoperable

### Course of Action for the Cholestech GDX System

If the Cholestech GDX System becomes inoperable, call Cholestech Technical Service at 800-733-0404 or 510-732-7200. Until the instrument becomes operable, venous specimens will be drawn and sent to the following reference laboratory.

Laboratory Name _____

Laboratory Address _____

_____

_____

Laboratory Phone No. _____

*or*

An alternative Cholestech GDX Analyzer will be used.

### Course of Action for Other Instruments in the Lab

Name of Instrument _____

Technical Service Phone Number _____

Written Procedure If the Instrument Fails _____

_____

_____



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### Course of Action for Other Instruments in the Lab

Name of Instrument

Technical Service Phone Number

Written Procedure If the Instrument Fails

## 1.11 Procedure Sign-Off

Approved

Director's Signature Date

Adopted

Director's Signature Date

Revised

Director's Signature Date

Discontinued

Director's Signature Date

The procedure is not applicable to this laboratory:

Director's Signature Date

## 1.12 Reference(s) and Bibliography

1. National Committee for Clinical Laboratory Standards. *Physician's Office Laboratory Procedure Manual; Tentative Guideline.* Villanova, Pa.: NCCLS; 1989. NCCLS publication POL2-T, Vol. 12, No. 5.

# 2.0 **Specimen Collection and Handling**

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# *Specimen Collection and Handling*

## 2.1 Introduction

Since the collection of the patient's specimen is the beginning of the analytical process, the use of proper collection techniques is essential to obtaining accurate results. It is imperative that laboratories follow appropriate biohazard and safety procedures.

Many laboratory errors can be traced to such nonanalytical factors as misidentifying or mishandling specimens. Nonanalytical error can be prevented by using careful collection and processing procedures.

## 2.2 Fingerstick Procedure

### Precautions

When handling patient samples, appropriate biohazard precautions should be taken. The Cholestech GDX A1C test is carried out on a fingerstick blood sample.

1. Choose a spot on the side of one of the *center* or ring fingers of either hand. The fingers and hands should be warm to the touch. To warm the hand, you can:
   a. Wash the patient's hand with warm water, or...
   b. Apply a warm (not hot) compress to the hand for several minutes, or...
   c. Gently massage the finger from the base to the tip several times to bring the blood to the fingertip.
2. Clean the site with an alcohol swab. **Dry thoroughly before pricking the finger.**
3. Firmly prick the selected site with a lancet.
4. Squeeze the finger gently to obtain a large drop of blood. Wipe away this first drop of blood as it may contain tissue fluid.
5. Squeeze the finger gently again while holding it downward until a second large drop of blood forms. **Do not milk the finger.** The puncture should provide a free-flowing drop of blood.
6. To collect the capillary blood sample, hold the MicroSafe Pipette horizontally. Touch the tip to the blood sample. **Do not squeeze.** The pipette will fill automatically to the black fill line. **Do not collect air bubbles.** If it is necessary to collect another drop of blood, wipe the finger with gauze then massage again from base to tip until a large drop of blood forms.
7. Wipe off any excess blood and have the patient apply pressure to the puncture until the bleeding stops.



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## 2.3 Procedure Sign-Off

Approved _____

Director's Signature Date

Adopted _____

Director's Signature Date

Revised _____

Director's Signature Date

Discontinued _____

Director's Signature Date

The procedure is not applicable to this laboratory:

_____

Director's Signature Date

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## 2.4 Venipuncture Procedure

### Precautions

This procedure should be conducted only by a qualified phlebotomist. When handling patient samples, follow appropriate biohazard precautions.

### Venipuncture Setup

1. Identify appropriate specimen type/types for the tests you are performing:

   - **Whole blood** – Anticoagulated whole blood containing white blood cells, red blood cells, platelets, and plasma.

2. Select appropriate tubes and needles needed for the tests.

COLOR-CODED TUBES

| Color | Use | Additive |
|---|---|---|
| **Green*** | Plasma or Whole Blood | Heparin |
| **Lavender*** | Plasma or Whole Blood | EDTA |
| Gray | Plasma or Whole Blood (glycolysis inhibition) | Oxalate/fluoride |
| Blue | Plasma or Whole Blood | Citrate |
| Red | Serum | None |
| Red or Red/Black | Serum | Serum separator gel |

3. When collecting several samples during a venipuncture, start with the tubes that have no additive, or a serum separator tube.

***Appropriate for use with the Cholestech GDX System.**



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### Performing the Venipuncture

1. Identify the patient by asking the patient to state his/her full name.
2. Label the tube with the patient's name or identification number.
3. Reassure the patient to make him or her comfortable.
4. Have the patient make a fist to increase blood flow.
5. Apply the tourniquet. Do not stop blood flowing in the veins for more than a minute before the blood is drawn as it causes venous occlusion. If necessary, release the tourniquet and reapply. Leaving the tourniquet on for more than three minutes may cause erroneous results.
6. Select the venipuncture site.
7. Clean the venipuncture site with a 70% isopropyl alcohol pad, making one smooth circular pass of the venipuncture site.
8. Allow the skin to dry to prevent hemolysis of the specimen and to prevent the patient from having a burning sensation when the venipuncture is performed. **Do not touch the venipuncture site after cleaning it.**
9. Perform the following procedure:

    - Grasp the patient's arm near the venipuncture site using your thumb to draw the skin tight.
    - With the needle bevel facing up, line up the needle with the vein. Penetrate the skin and enter the vein at an angle of approximately 45º.
    - Holding the flange of the needle holder, push the tube forward until the back end of the needle punctures the stopper. While the needle is in the vein, keep the tube below the puncture site.
    - When the blood starts flowing into the tube, release the tourniquet and open the patient's hand. This allows circulation to return to normal and reduces bleeding at the venipuncture site. When drawing multiple tubes, keep the tourniquet in place until the last tube is being collected.
    - Keep constant, forward pressure on the tube (in the direction of the needle); this prevents the shutoff valve from closing and stopping the flow of blood.
    - When the blood stops flowing, remove the tube from the holder. The needle's shutoff valve will stop the blood flow until the next tube is inserted.
    - Tubes containing an anticoagulant should be allowed to fill until the vacuum is exhausted and blood flow ceases (this assures the correct ratio of anticoagulant to blood volume). Gently invert the tube five to ten times to mix the blood and anticoagulant. **Do not shake the tube vigorously.**
    - Insert the next tube into the holder and repeat the collection procedure.

**If a blood sample cannot be obtained, change the position of the needle. If the needle has penetrated too far into the vein, pull it back a bit. If it has not penetrated far enough, move it farther into the vein. If this does not help, try inserting another evacuated tube.**

10. Remove the needle and bandage the site.

    - After the tube has been withdrawn from the holder, gently remove the needle from the venipuncture site. Immediately apply a sterile gauze pad to the site, and tell the patient to keep pressure on the site for two minutes.
    - Apply an adhesive or gauze bandage over the venipuncture site after the bleeding has stopped. The patient should leave the bandage on for a minimum of 15 minutes.

11. Dispose of the puncture unit. To prevent injury and to be sure needles are not reused, promptly dispose of the needle and the blood tube holder in an appropriate biohazard container. *Do not recap the needle.*

O

## 2.5 Procedure Sign-Off

Approved _____
Director's Signature Date

Adopted _____
Director's Signature Date

Revised _____
Director's Signature Date

Discontinued _____
Director's Signature Date

The procedure is not applicable to this laboratory:

_____
Director's Signature Date



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## 2.6 Reporting Results Properly

You may wish to establish a procedure that will prevent any misidentification when giving the results to the physician or patient. The following space is available to record the laboratory procedure that will be used to report results from the Cholestech GDX System. Or you may use the **A1C Result Log** in the *Master Forms* section.

The additional space that follows is available to document the procedures for other instruments in the laboratory.

Cholestech GDX System

Instrument Name Manufacturer



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## 2.7 Procedure Sign-Off

Approved _____
Director's Signature Date

Adopted _____
Director's Signature Date

Revised _____
Director's Signature Date

Discontinued _____
Director's Signature Date

The procedure is not applicable to this laboratory:

_____
Director's Signature Date

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## 2.8 Proper Specimen Storage

1. Anticoagulated blood may be sampled directly from the tube after mixing. Use a MiniPet™ Pipette and tips or a micropipetter calibrated to deliver 10 µL.

2. Mix all samples thoroughly by gentle inversion 7–8 times before testing.

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## 2.9 Procedure to Properly Remove a Rubber Stopper from an Evacuated Tube

1. All blood samples and blood products are potentially biohazardous and should be treated as such. Latex gloves, goggles and a completely buttoned long-sleeve lab coat should be worn when handling these materials.

2. When removing rubber stoppers from evacuated tubes, cover the stopper with a piece of gauze, or remove with an evacuated tube stopper remover.

3. Always point the tops of any sample tubes away from anyone when removing the caps. Pipette tips are pointed away from people while the tips are being ejected.

4. For cleanup of spilled blood and blood products, observe the safety policies in the lab and the Universal Precautions recommended by the Occupational Safety & Health Administration (OSHA).



I For Information Only R Recommended O Optional Information

## 2.10 Reference(s) and Bibliography

1. National Committee for Clinical Laboratory Standards. *Physician's Office Laboratory Procedure Manual; Tentative Guideline.* Villanova, Pa.: NCCLS; 1989. NCCLS publication POL2-T, Vol. 12, No. 5.

2. National Committee for Clinical Laboratory Standards. *Procedure for the Collection of Diagnostic Blood Specimens by Skin Puncture.* 2nd ed. Approved Standards, NCCLS.

3. Tietz NW, ed. *Fundamentals of Clinical Chemistry.* Philadelphia, Pa.: WB Saunders Co; 1987.

4. National Committee for Clinical Laboratory Standards. *Protection of Laboratory Workers from Infectious Disease Transmitted by Blood, Body Fluids, and Tissue; Tentative Guideline.* Villanova, Pa.: NCCLS; 1991. NCCLS document M29-T2 (ISBN 1-56238-123-7).

5. Davidsohn I, Henry JB, eds. *Todd-Sanford Clinical Diagnosis by Laboratory Methods.* Philadelphia, Pa.: WB Saunders Co; 1969.

6. Burtis CA, Ashwood ER, eds. *Tietz Textbook of Clinical Chemistry.* 3rd ed. Philadelphia, Pa.: WB Saunders Co; 1999.

# 3.0 **Quality Control**

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# *Quality Control*

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## 3.1 Introduction

Quality control refers to the testing done to show that a system is working properly and giving dependable results.

The quality control materials (controls) sold by Cholestech are those recommended for use with the Cholestech GDX System.

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## 3.2 Handling Controls

- Read the product insert that comes with each box of controls to find out how to use and store them.
- Check the expiration date before using. **Do not use control material past its expiration date.**
- Allow an adequate amount of time for the lyophilized control sample to completely dissolve (minimum: 15 minutes).
- Verify that the lot number on the control vial and the assay sheet are the same.

R

## 3.3 External Quality Control

External controls must be used to demonstrate that the reagents and assay procedure perform properly.

Cholestech GDX A1C Controls are available from Cholestech. One set of controls has normal and abnormal A1C control samples. Controls must be tested:

- With each new shipment of test cartridges (even if cartridges are from the same lot previously received).
- With each new lot of test cartridges.
- As otherwise required by your laboratory's standard quality control procedures.
- If you are not running the Cholestech GDX under CLIA-waived status, or if your local or state regulations require more frequent testing of quality control material, then quality control must be performed in compliance with those regulations.

Good Laboratory Practice principles suggest that external controls must be run whenever the laboratory director has any question about test system integrity or operator technique (e.g., when reagents may have been stored or handled in a way that can degrade their performance or when operators have not performed a particular test in recent weeks).

If the controls do not perform as expected, repeat the test or contact Cholestech Technical Service before testing patient samples.

**The quality control results must be in range before testing patient samples. See Section 3.4 that follows if quality control results are not within range.**

**Please call Cholestech Technical Service at 800-733-0404 if you have any questions about quality control.**



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## 3.4 Control Range

Results for Cholestech GDX A1C Controls must be within the ranges included with the controls before patient samples are tested.

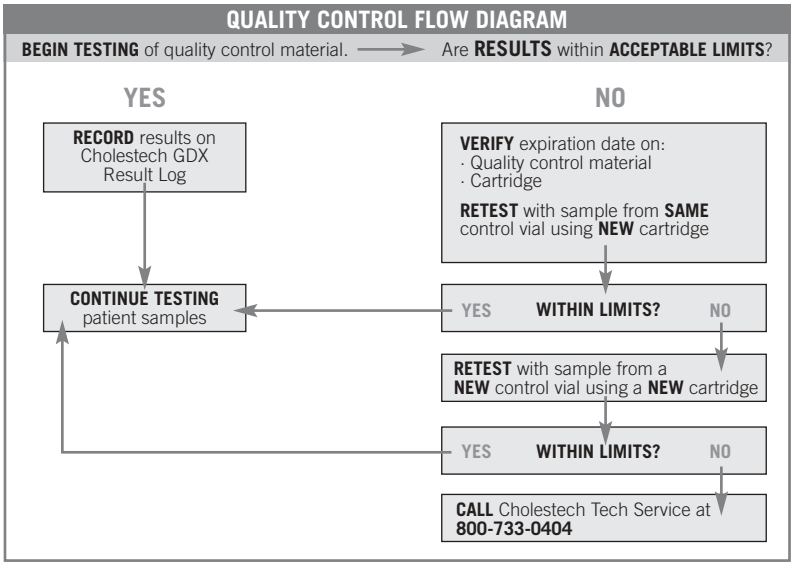
### Results Within the Control Range

QC results can be logged on the Quality Assurance Record template found in the *Master Forms* section. If a result for an A1C test cartridge is within the expected ranges, patient samples may be tested and the results reported.

### Results Outside the Control Range

If results of one or both levels of control tested are outside the established ranges:

1. Verify that you have the correct assay sheet for the control being tested.
2. Check that the expiration date for the test cartridge and quality control materials have not passed.
3. Verify that the lot number on the control vial and the assay sheet are the same.
4. Retest the control level that is out of range using a new sample from the same control vial. Pay careful attention to possible errors in technique.
   a. If the control is within acceptable limits, patient samples may be tested and results reported.
   b. If the control is outside the acceptable limits, retest with a sample of control from a new vial.
      - If results are in range, continue testing patient samples.
      - If the control is still outside the acceptable limits, contact Cholestech Technical Service. Do not use the Analyzer for testing patient samples until the problem is resolved.



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# 4.0 **A1C Test Procedure**

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# *A1C Test Procedure*

## 4.1 Introduction

The test procedures in this section are designed specifically for tests run on the Cholestech GDX System. Instructions are provided for testing fingerstick, venipuncture or control samples.

## 4.2 Medical Importance

Diabetes mellitus is a leading cause of kidney failure, blindness and amputation in adults. It is also a major risk factor for heart disease, stroke and birth defects and shortens average life expectancy by up to 15 years. It is now well accepted that in patients with diabetes there is a direct relationship between blood sugar levels and complications associated with the disease. In a number of studies, such as the Diabetes Control and Complications Trial[1] (DCCT) and the United Kingdom Prospective Diabetes Study,[2] it was conclusively shown that a reduction in blood sugar levels significantly delayed the onset and slowed the progression of the most serious complications of diabetes.

The measurement of A1C is recommended for monitoring the long-term care of people with diabetes[3,4] because the concentration of A1C within a red blood cell reflects the average level of blood sugar over the previous 120 days. The level of A1C therefore rises proportionately in patients with higher levels of blood sugar, such as those with uncontrolled or undiagnosed diabetes.[5,6] It has been proposed that the measurement of A1C may be useful in the diagnosis of diabetes.[7,8]

## 4.3 Principle of the Test

The Cholestech GDX Analyzer uses boronate affinity chromatography to separate the glycated hemoglobin fraction from the nonglycated fraction. Both fractions are measured and an algorithm converts the results into the percentage A1C (hemoglobin A1C) in the sample.

After a GDX test cartridge has been placed into the instrument, a small sample of blood is added to the first (red-capped) sample tube, which contains the boronate affinity resin. The red blood cells are instantly lysed to release the hemoglobin and the boronate affinity resin binds the glycated hemoglobin. After a short incubation step, the liquid is poured into the funnel of the test cartridge and the non-glycated fraction is collected in an optical chamber (cuvette), where the hemoglobin concentration is photometrically measured. The glycated hemoglobin remains bound to the boronate affinity resin, which sits at the bottom of the test cartridge funnel. The boronate affinity resin/glycated hemoglobin is then washed with the contents of the second (blue-capped) tube. The final step is the elution of the glycated hemoglobin off the boronate affinity resin using the third (clear-capped) tube. The glycated hemoglobin concentration is measured and the Analyzer calculates the A1C in the sample.

Active Ingredients:
M-amino-phenyl boronic acid coupled to 6% beaded agarose ~ 100 mg



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### Cartridge Storage

Cartridges must not be stored upside down.

Cartridges may be used until the date printed on the rim when stored at 59–77ºF (15–25ºC). Do not freeze the test cartridges.

### Sample Handling

Sample Volume:
10 µL of whole blood

Fingerstick whole blood sample with MicroSafe™ Pipette. (MicroSafe Pipettes included with each box of test cartridges.) **No anticoagulant in the MicroSafe Pipettes.**

Venous whole blood in heparin and EDTA tubes only. (For venous samples or controls, use the 10 µL MiniPet™ Pipette supplied with the system; uses 11-010 pipette tips.) Venous samples can be used up to 4 days after collection when stored at 36–46ºF (2–8ºC). **Hemolyzed or packed red blood cells samples must not be used.**

**Precaution:** All blood samples and containers, capillary tubes and materials that have come in contact with blood should be handled as if capable of transmitting infectious disease and discarded into a biohazard waste container after use.

### Calibration

The Cholestech GDX Analyzer and A1C Test Cartridges have been manufactured to deliver an A1C result. This is calibrated to the recommendations of the Diabetes Control and Complications Trial (DCCT). This result is traceable to the NGSP (National Glycohemoglobin Standardization Program), an internationally accepted method of standardization. The DCCT was a landmark multicenter clinical study that conclusively linked elevated A1C levels to the complications associated with diabetes. Further information on calibration can be found in the Cholestech GDX Analyzer User Manual.

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## 4.4 Procedure

### Materials Required

- Cholestech GDX Analyzer and power supply
- A1C test cartridge
- MicroSafe Pipette (10 µL)
- Alcohol swabs and gauze for cleaning puncture site
- Lancets for capillary blood collection
- Latex gloves
- Biohazard waste containers
- Quality control material
- MiniPet Pipette (10 µL) or micropipetter that will deliver 10 µL for use with venipuncture samples and quality control material
- Vacuum collection tubes, needles and tube holders if sample is to be collected by venipuncture



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## Running a Test

For more information, see the test cartridge package inserts. The Quick Reference Guide gives a brief summary of the procedures.

**Note:** If the Cholestech GDX Analyzer has not been plugged in and has not been stored at room temperature, a warm-up period will occur at initial setup. The maximum time required for warm-up is 10 minutes. If the Analyzer fails to warm up in this period, an error message will appear on the display. (See the *Troubleshooting* section of this manual.)

When the Analyzer is ready for use, the Insert and Cartridge icons will flash. The "left" and "right" arrows will be solid.

You can now use the Analyzer to run an Optics Check Cartridge or perform an A1C test.

## Procedure A1C Test

1. Unpack a Cholestech GDX A1C Test Cartridge. Hold the cartridge by the white rim only and place it into the Analyzer, ensuring that the protruding tab on the test cartridge is aligned with the corresponding notched guide on the cartridge well. Push it down until it clicks into place ***(see Figure 1)***. The Analyzer will then check that the test cartridge is OK. During this time the Hourglass icon will appear on the display.

   When this check is complete, a beep is heard and the light will flash at Position 1. The Analyzer will show the Identification Number icon with a test identification number ***(see Figure 2)***. This unique identification number will be stored in the Analyzer's memory with the test result. You can access this information at a later date if required (see instructions in the Cholestech GDX Analyzer User Manual). Write down the identification number with your test result.

**Figure 1**

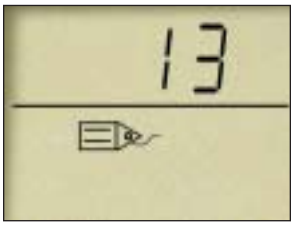


**Figure 2**

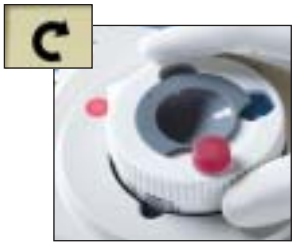

**Figure 3**



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**IMPORTANT: Gloves should be worn whenever working with samples that are potentially biohazardous.**

2. Hold the white rim of the test cartridge and rotate it clockwise through 90º to Position 1 ***(see Figure 3)***. The test cartridge will click into its new position. The first sample tube will rise from the cartridge. Remove the sample tube from the test cartridge and unscrew the cap.
   - Choose a spot that is on the side of one of the *center* or ring fingers of either hand. The fingers and hands should be warm to the touch. To warm the hand, you can:
     a. Wash the patient's hand with warm water, or…
     b. Apply a warm (not hot) compress to the hand for several minutes, or…
     c. Gently massage the finger from the base to the tip several times to bring the blood to the fingertip.
   - Clean the site with an alcohol swab. **Dry thoroughly before pricking the finger.**
   - Firmly prick the selected site with a lancet.
   - Squeeze the finger gently to obtain a large drop of blood.
   - Wipe off the first drop of blood. Hold the MicroSafe Pipette next to the blood drop on your finger ***(see Figure 4)***, leaving the pipette in contact with the blood until the blood reaches the fill line ***(see Figure 5)***. Do not squeeze the bulb while filling the capillary as this will lead to an overfilled MicroSafe Pipette ***(see Figure 6)***. Do not cover the air hole before the sampling is complete, as this will cause incorrect filling of the pipette ***(see Figure 7)***.
   - Place the tip of the MicroSafe Pipette of blood into the liquid of the sample tube. Squeeze the bulb to release the blood. Replace the cap and mix the contents by gently turning upside down 5 TIMES ***(see Figure 8)***. Start the wait time by IMMEDIATELY PRESSING the round Enter button ***(see Figure 9)***. A 60-second countdown will appear on the display.

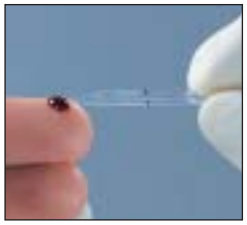
**Figure 4**

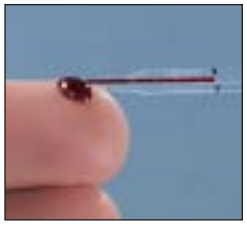
**Figure 5**

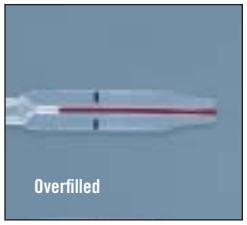

**Figure 6**

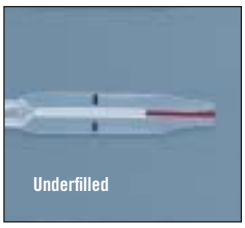

**Figure 7**

**Figure 8**

**Figure 9**



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3. Put everything that touched the blood sample or control in a biohazard waste container.

4. The end of the countdown is indicated by a beep. The Insert/Mix and Pour Tube icons will appear on the display. Mix the contents of the tube by turning upside down 3 TIMES ***(see Figure 10)***. Remove the cap. Pour the entire contents into the gray funnel of the test cartridge ***(see Figure 11)***.

5. The Analyzer senses the sample. No button press is necessary.
   - A 50-second countdown will appear on the display.
   - At the end of the countdown, the Hourglass icon will appear.
   - A beep will sound. The light will flash at Position 2 and the Rotate Cartridge icon will appear on the display.

**Note:** Some liquid may stay in the funnel at the end of the 50-second countdown. Continue and turn the cartridge to Position 2. Wait until the liquid disappears from the funnel before adding the contents of the second tube.

6. Hold the white rim of the cartridge and turn it clockwise to Position 2 ***(see Figure 12)***. The test cartridge will click into its new position and the second tube will rise from the cartridge.
   - Remove the tube from the cartridge.
   - Unscrew the cap.
   - Pour the entire contents into the funnel of the test cartridge ***(see Figure 13)***.
   - Now press the enter button.

   A 40-second countdown will appear on the display. The liquid will gradually disappear into the test cartridge.

**Figure 10**

**Figure 11**

**Figure 12**

**Figure 13**



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7. At the end of the countdown, a beep is heard. The light will flash at Position 3. The Rotate Cartridge icon will appear on the display.
   - Hold the white rim of the test cartridge and turn it clockwise to Position 3 ***(see Figure 14)***. The cartridge will click into its new position. The third tube will rise from the cartridge.
   - When prompted by the Pour Tube icon, remove the tube from the cartridge ***(see Figure 15)***. Pour the entire contents into the funnel. Again, the Analyzer senses the liquid. The beep continues for up to 20 seconds while the Analyzer takes a reading. The final 80-second countdown will then appear on the display.

8. At the end of the countdown, the Hourglass icon will appear on the display.

   Do not turn the cartridge until the beep sounds and the Rotate Cartridge icon appears on the display.
   - Turn the test cartridge clockwise to Position 0 ***(see Figure 16)***.
   - Remove it from the Analyzer ***(see Figure 17)***.

   Put the test cartridge in a biohazard waste container. When the test cartridge is removed, the Analyzer displays the percentage A1C value for the sample.
   - Push the enter button to clear the display.

   Please call Cholestech Technical Service at 800-733-0404 if you have any questions about the operation of the Cholestech GDX System.

**Figure 14**

**Figure 15**

**Figure 16**

**Figure 17**

## 4.5 Test Interpretation

The ADA recommends that the goal of therapy should be an A1C result of <7% and that physicians should reevaluate and, in most cases, significantly change the treatment regimen in patients with A1C test results consistently >8%. These specific A1C values apply only to assay methods that are certified as traceable to the DCCT reference method.

### Limitations

#### Linearity and Temperature Effects

The Cholestech GDX test has been shown to give a linear response from 4–15% A1C using patient samples. In addition, the theoretical performance of the test indicates a linear range of 2% to >25% A1C. Cholestech GDX results were shown not to be affected by operating temperatures of 63–86ºF (17–30º C).

#### Hemoglobin and Hematocrit

The Cholestech GDX test performs acceptably over a hemoglobin range of 8–20 g/dL and hematocrit of 30% to 60%.

### Abnormal Hemoglobins

Abnormal hemoglobin (Hb) variants (e.g., HbS, HbC, and HbE) and chemically modified derivatives (e.g., carbamyl-Hb) can cause interference and dramatically affect the results of A1C measurement. Such problems should be suspected whenever A1C results are not in agreement with results of self-monitoring of blood glucose. The Cholestech GDX System has virtually no interference from hemoglobin variants because the method uses boronate affinity chromatography to separate the glycated hemoglobin fraction from the nonglycated fraction.

Nearly 8% of African Americans carry the HbS trait and 2.3% carry HbC. In sub-Saharan Africa, prevalence of these two is up to one-third of all patients. HbE can be as high as 30% in Southeast Asia. HbF can reach 30% in individuals with hereditary persistence. Chemically modified Hbs may be chronically present in diabetic patients. Carbamylated Hb is the most commonly encountered of these.[9]

Patients in whom the lifespan of the red blood cell is significantly shortened, e.g., hemolytic anemia, affect all A1C testing methods.[10]

### Interfering Substances

The following substances at the levels indicated were shown to have no effect on the Cholestech GDX test results:

| Substance Concentration (mg/dL) | |
|---|---|
| Bilirubin | 8.5 mg/dL |
| Acetylsalicylic acid | 30.0 mg/dL |
| Caffeine | 30.0 mg/dL |
| Acetaminophen | 30.0 mg/dL |
| Hydroxyzine dihydrochloride | 30.0 mg/dL |

Triglycerides at 761 mg/dL showed no effect on the Cholestech GDX test result, but elevated lipid concentrations may interfere and cause low results in this type of assay.

### Expected Results

Nondiabetic children and adults have an average A1C of 5%, with a range of 3% to 7%.[5] People with diabetes can have values that are much higher, and the A1C level reflects the degree of control of the disease.

### Accuracy and Precision

The Cholestech GDX has met the accuracy and precision requirements set by the NGSP in each year it has been tested. Cholestech GDX A1C results are certified as traceable to the DCCT.

NGSP precision: <4% coefficient of variation (CV) by NCCLS EP5-A protocol.
NGSP bias: 95% confidence interval of differences between Cholestech GDX and NGSP reference laboratory values are within ±1% of NGSP reference laboratory values.

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## 4.6 Technical Assistance

For technical assistance, please call Cholestech Technical Service at 800-733-0404.

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## 4.7 Procedure Sign-Off

Approved _____
Director's Signature Date

Adopted _____
Director's Signature Date

Revised _____
Director's Signature Date

Discontinued _____
Director's Signature Date

The procedure is not applicable to this laboratory:

_____
Director's Signature Date



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## 4.8 Reference(s) and Bibliography

1. The Diabetes Control and Complications Trial Research Group. *N Engl J Med* 1993; 329:977–986.

2. United Kingdom Prospective Diabetes Study Group. *Lancet* 1998; 352:837–853.

3. Sperling MA et al. *Physicians Guide to Insulin-Dependent (Type 1) Diabetes: Diagnosis and Treatment.* Alexandria, Va.: 1966. American Diabetes Association, Inc.; 44–45.

4. Sox Int. Ed.: *Common Diagnostic Tests: Use and Interpretation.* 2nd ed. Philadelphia, Pa.: 1990. American College of Physicians; 122, 133–134, 139–140.

5. Koenig RJ, Peterson CM, Jones RL, Saudek C, Lehman M et al. Correlation of glucose regulation and hemoglobin A1C in diabetes mellitus. *N Eng J Med* 1976; 295:417–420.

6. Gabbay KH, Hasty K, Breslow JL et al. Glycosylated hemoglobins and long-term blood glucose control in diabetes mellitus. *J Clin End Metab* 1977; 44(5):859–864.

7. McCanoe DR, Hanson RL et al. Comparison of tests for glycated haemoglobin and fasting two hour plasma glucose concentration as diagnostic methods for diabetes. *Brit Med J* 1994; 906:1323–1328.

8. Peters AL, Davidson MB et al. A clinical approach for the diagnosis of Diabetes mellitus; An analysis using glycosylated haemoglobin levels. *JAMA* 1998; 276(15):1246–1252.

9. Goldstein DE, Little RR, Lorenz RA, Malone JI et al. Tests of glycemia in diabetes. *Diabetes Care* 1995; 18:896–909.

10. Roberts WL, De BK, Brown D, Hanbury CM et al. Effects of hemoglobin C and S traits on eight glycohemoglobin methods. *Clin Chem* 2002; 48:383–385.

# 5.0 **Safety**

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# *Safety*

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## 5.1 Introduction

The Occupational Safety & Health Administration (OSHA) ruled that beginning March 6, 1992, all labs must undergo training to protect the workers from bloodborne pathogens. The new regulations outline in detail what employees must be taught about the hazards of working with potentially infectious materials and what precautions must be taken to prevent or minimize exposure. All biosafety training must be documented with dates, summary of content per each class, names and qualifications of all instructors, and the names and job titles of employees who attend.[1]

OSHA also has required that as of May 5, 1992, every employer will have a written plan designed to eliminate or minimize worker exposure. This includes an outline of the employer's hepatitis B vaccination program. Employers are required to offer, at their expense, a vaccine to any worker who may at any time be exposed to potential infectious materials. Staff members may waive their right to the vaccine by signing a form, but they are entitled to change their minds and receive the vaccine as soon as possible.[1]

You may use this section to file any training material, forms, or guidelines regarding lab safety practices. For further information or to obtain training material regarding these regulations, contact OSHA.

Reprints of the final rule, "Occupational Exposures to Blood Borne Pathogens," can be obtained by contacting this organization:

**OSHA Office of Publications**
U.S. Department of Labor
P.O. Box 37535
Washington, DC 20013-7535
Web site: **www.osha.gov**

Another excellent source of reference is the National Committee for Clinical Laboratory Standards (NCCLS). The NCCLS is a U.S. organization developing standards for clinical laboratory testing. For further information, you may contact this organization:

**National Committee for Clinical Laboratory Standards**
940 West Valley Road, Suite 1400
Wayne, PA 19087-1898
610-688-0100, Fax 610-688-0700
e-mail: **exoffice@nccls.org**
Web site: **www.nccls.org**

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## 5.2 Reference(s) and Bibliography

1. Brown JW, Blackwell H. Complying with the new OSHA regs on HIV and HBV protection. *Medical Laboratory Observer* June 1992; 21.



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# 6.0 **Training**

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# *Training*

## 6.1 Introduction

In the *Master Forms* section of this manual, Cholestech has included various forms to support your training requirements.

## 6.2 Cholestech GDX Training Checklist

This checklist is designed to assist the trainer in training users of the Cholestech GDX System. There is room to date and sign each procedure as the task is completed.

## 6.3 Certificate of Training—Fingerstick Blood Collection

This certificate can be used to document that fingerstick training has been completed and approved by a physician. You can file the certificates in this section as proof of documented training if it is required by regulations in your area.

## 6.4 Online Training

Training is available at the Cholestech Web site: **www.cholestech.com.**

# 7.0 Material Safety Data Sheets

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# *Material Safety Data Sheets*

OSHA requires all businesses that manufacture chemical-based products and distribute them through interstate shipment to have a Material Safety Data Sheet (MSDS).

The information contained on an MSDS describes any potential hazards and any special handling required for chemical products.

*The standard format for an MSDS is as follows:*

1. Identity
2. Hazardous Ingredients
3. Physical Data
4. Fire & Explosion Data
5. Health Information
6. Reactivity Data
7. Spill or Leak Procedures
8. Personal Protection Information
9. Special Precautions

MSDSs for Cholestech GDX test cartridges, controls, and Optics Check Cartridges are included here.

# MATERIAL SAFETY DATA SHEET

CHOLESTECH

**Cholestech GDX™ A1C Test Cartridges**

## SECTION 1 – IDENTITY

| NAME | | ADDRESS |
|---|---|---|
| Cholestech GDX™ System | | 3347 Investment Blvd., Hayward, CA 94545 |
| **TELEPHONE NUMBER** | **FOR ADDITIONAL INFORMATION CONTACT** | **DATE PREPARED** |
| 800-733-0404 | Technical Service | June 21, 2002 |
| **COMMON NAME (USED ON LABEL)** | | **CHEMICAL FAMILY** |
| Cholestech GDX A1C Test Cartridges | | Does not apply |
| **CHEMICAL NAME** | | **FORMULA** |
| Does not apply | | Does not apply |
| **TRADE NAME & SYNONYMS** | | |
| Cholestech GDX,™ Trademark of Cholestech Corporation | | |

## SECTION 2 – HAZARDOUS INGREDIENTS

| HAZARDOUS COMPONENT | CAS # | % (wt) | TLV | PEL |
|---|---|---|---|---|
| Sample Buffer | | | | |
| Sodium Azide | 26628-22-8 | 0.1% w/v | | |
| Triton X-100 | 9002-93-1 | 0.02% w/v | | |
| Hepes/sodium Hepes | 7365-45-9 | 0.5% w/v | | |
| Magnesium Chloride | 7791-18-6 | <1% w/v | | |
| Wash Buffers | | | | |
| Sodium Azide | 26628-22-8 | 0.1% w/v | | |
| Hepes/sodium Hepes | 7365-45-9 | 0.5% w/v | | |
| Magnesium Chloride | 7791-18-6 | <1% w/v | | |
| Elution Buffer | | | | |
| Phenoxyethanol | 64-19-7 | 0.5% v/v | | |
| Ammonium Acetate | 631-61-8 | 2% w/v | | |
| Magnesium Chloride | 7791-18-6 | 1% w/v | | |
| Ultrawet 60 | | <0.001% v/v | | |

PEL: Permissible Exposure Limit established by the Occupational Safety & Health Administration (OSHA).
TLV: Threshold Limit Value established by the American Conference of Governmental Industrial Hygienists, 1987–88.

## SECTION 3 – PHYSICAL DATA

| BOILING POINT | SPECIFIC GRAVITY | | VAPOR PRESSURE |
|---|---|---|---|
| Not determined | ($H_20 = 1$) | | (mm Hg) |
| | Boronate Agarose 6XL | N/A | Not determined |
| | Sodium Azide | 1.85 | |
| | Triton X-100 | 1.07 | |
| | Hepes/Sodium Hepes | N/A | |
| | Magnesium Chloride | 1.57 | |
| | Phenoxyethanol | 1.10 | |
| | Ammonium Acetate | 1.07 | |
| | Ultrawet 60 | 1.02 | |

| PERCENT VOLATILE BY VOLUME (%) | VAPOR DENSITY (AIR=1) | EVAPORATION DATE (_____ - 1) |
|---|---|---|
| Not determined | Not determined | Not determined |
| **SOLUBILITY IN WATER** | | **REACTIVITY IN WATER** |
| Some components are soluble | | Not determined |
| **APPEARANCE AND ODOR** | | |
| Clear, no odor | | |

## SECTION 4 – FIRE AND EXPLOSION DATA

| FLASH POINT | FLAMMABLE LIMITS IN AIR (% by VOLUME) |
|---|---|
| Not determined | LOWER: Not determined UPPER: Not determined |
| **EXTINGUISHING MEDIA** | **AUTO IGNITION TEMPERATURE** |
| Sample, Wash and Elution Buffers:<br>Water, dry powder, carbon dioxide or appropriate foam may be used to extinguish.<br>Plastic Mouldings:<br>Water, dry powder, carbon dioxide or appropriate foam may be used to extinguish. | Not determined |

**UNUSUAL FIRE AND EXPLOSION HAZARDS**

Aqueous solution is not flammable but residue may emit toxic fumes on combustion. Plastic components are flammable.

**SPECIAL FIRE-FIGHTING PROCEDURES**

None

*Continued on next page.*

## MATERIAL SAFETY DATA SHEET CONTINUED

CHOLESTECH

### SECTION 5 – HEALTH INFORMATION

**PRIMARY ROUTES OF EXPOSURE**

Skin, eye, ingestion

**SIGNS AND SYMPTOMS OF EXPOSURE**

(1) ACUTE OVEREXPOSURE – None
(2) CHRONIC OVEREXPOSURE – None

**MEDICAL CONDITIONS GENERALLY AGGRAVATED BY EXPOSURE**

None

| CHEMICAL/COMPONENT LISTED AS CARCINOGEN OR POTENTIAL CARCINOGEN | NTP | IARC | OSHA |
|---|---|---|---|
| None | ___ Yes<br>___ No | ___ Yes<br>___ No | ___ Yes<br>___ No |

**OTHER EXPOSURE LIMITS**

None

**EMERGENCY & FIRST AID PROCEDURES**

Eye Contact – Irrigate eye for 10 minutes with water. Obtain medical attention.
Skin Contact – Wash off shin with water. Remove and wash contaminated clothing.
Ingestion – Harmful if swallowed. Wash out mouth with water. Drink plenty of water. Obtain medical attention.

### SECTION 6 – REACTIVITY DATA

| STABILITY | CONDITIONS TO AVOID |
|---|---|
| Unstable ___ Stable _X_ | Not determined |

**INCOMPATIBILITY (MATERIALS TO AVOID)**

Not determined

**HAZARDOUS DECOMPOSITION PRODUCTS**

Not determined

| HAZARDOUS POLYMERIZATION | CONDITIONS TO AVOID |
|---|---|
| May Occur ___ Will Not Occur _X_ | Product performance will be impaired if stored for over 2 weeks at temperatures above ambient temperature. Functionality is not impaired after short periods (<2 days) at temperatures up to 131°F (55°C). |

### SECTION 7 – SPILL OR LEAK PROCEDURES

**STEPS TO BE TAKEN IN CASE MATERIAL IS LEAKED OR SPILLED**

Sample, Wash and Elution Buffers – Wear protective gloves. If local regulations permit, mop up and rinse to waste with copious flow of water. Otherwise absorb on inert absorbent and transfer to biohazardous waste container for collection by waste contractor.
Sample, Wash and Elution Buffers contaminated with blood – Wear protective gloves. Absorb on inert absorbent and transfer to biohazardous waste container for collection by waste contractor. Clean surfaces with disinfectant.

**WASTE DISPOSAL METHOD**

Dispose of wastes in accordance with Federal, State, and Local codes.
Used test cartridges are biohazardous as the infectivity of the blood sample cannot be known before use. The product must be disposed of as biohazardous waste.

### SECTION 8 – PERSONAL PROTECTION INFORMATION

**RESPIRATORY PROTECTION**

Not required under normal and intended uses

**VENTILATION**

General room ventilation

| PROTECTIVE GLOVES | EYE PROTECTION |
|---|---|
| During the test procedures and while collection or handling patient's blood sample wear protective gloves. | Not required |

**OTHER PROTECTIVE CLOTHING OR EQUIPMENT**

None

### SECTION 9 – SPECIAL PRECAUTIONS

**PRECAUTIONS TO BE TAKEN IN HANDLING & STORING**

Store and handle according to packaged instructions. The product is not classified as requiring any special considerations and does not present any hazards during shipment.

**OTHER PRECAUTIONS**

No environmental hazard is anticipated provided the materials are handled and disposed of with due care and attention.

# MATERIAL SAFETY DATA SHEET

CHOLESTECH

**Cholestech GDX™ A1C Controls**

## SECTION 1 – IDENTITY

| NAME | | ADDRESS |
|---|---|---|
| Cholestech GDX™ System | | 3347 Investment Blvd., Hayward, CA 94545 |
| **TELEPHONE NUMBER** | **FOR ADDITIONAL INFORMATION CONTACT** | **DATE PREPARED** |
| 800-733-0404 | Technical Service | June 21, 2002 |
| **COMMON NAME (USED ON LABEL)** | | **CHEMICAL FAMILY** |
| Cholestech GDX A1C Controls | | Does not apply |
| **CHEMICAL NAME** | | **FORMULA** |
| Does not apply | | Does not apply |
| **TRADE NAME & SYNONYMS** | | |
| Cholestech GDX™, Trademark of Cholestech Corporation | | |

## SECTION 2 – HAZARDOUS INGREDIENTS

| HAZARDOUS COMPONENT | CAS # | % (wt) | TLV | PEL |
|---|---|---|---|---|
| Product consists of freeze-dried whole human blood. Product is reconstituted with 500 µL of purified water. | | | | |

PEL: Permissible Exposure Limit established by the Occupational Safety & Health Administration (OSHA).
TLV: Threshold Limit Value established by the American Conference of Governmental Industrial Hygienists, 1987–88.

## SECTION 3 – PHYSICAL DATA

| BOILING POINT | SPECIFIC GRAVITY | VAPOR PRESSURE |
|---|---|---|
| Not applicable | Not determined | (mm Hg)<br>Not determined |

| PERCENT VOLATILE BY VOLUME (%) | VAPOR DENSITY (AIR=1) | EVAPORATION DATE (_____- 1) |
|---|---|---|
| Not determined | Not determined | Not determined |

| SOLUBILITY IN WATER | REACTIVITY IN WATER |
|---|---|
| Soluble – 500 µL of purified water is used to reconstitute controls prior to use. | Not applicable |

**APPEARANCE AND ODOR**

Form – solid powder
Color – red (stored in brown glass bottles)
Odor – none

## SECTION 4 – FIRE AND EXPLOSION DATA

| FLASH POINT | FLAMMABLE LIMITS IN AIR (% by VOLUME) |
|---|---|
| Not applicable | LOWER: Not applicable UPPER: Not applicable |
| **EXTINGUISHING MEDIA** | **AUTO IGNITION TEMPERATURE** |
| Not flammable or explosive | Not applicable |

**UNUSUAL FIRE AND EXPLOSION HAZARDS**

Not flammable or explosive

**SPECIAL FIRE-FIGHTING PROCEDURES**

None

## SECTION 5 – HEALTH INFORMATION

**PRIMARY ROUTES OF EXPOSURE**

Skin, eye, ingestion

**SIGNS AND SYMPTOMS OF EXPOSURE**

**MEDICAL CONDITIONS GENERALLY AGGRAVATED BY EXPOSURE**

None

| CHEMICAL/COMPONENT LISTED AS CARCINOGEN OR POTENTIAL CARCINOGEN | NTP | IARC | OSHA |
|---|---|---|---|
| None | ___ Yes<br>___ No | ___ Yes<br>___ No | ___ Yes<br>___ No |

**OTHER EXPOSURE LIMITS**

None

**EMERGENCY & FIRST AID PROCEDURES**

Eye Contact – Irrigate with copious amount of water. Week medical advice.
Skin Contact – Wash off thoroughly with soap and water. Seek medical advice.
Ingestion – Wash out mouth thoroughly with water. Seek medical advice.
Inhalation – Not applicable.

*Continued on next page.*

## MATERIAL SAFETY DATA SHEET CONTINUED

CHOLESTECH

### SECTION 6 – REACTIVITY DATA

| STABILITY | CONDITIONS TO AVOID |
|---|---|
| Unstable ___ Stable **X**<br>Non-reactive | Not determined |

**INCOMPATIBILITY (MATERIALS TO AVOID)**

Not determined

**HAZARDOUS DECOMPOSITION PRODUCTS**

Not determined

| HAZARDOUS POLYMERIZATION | CONDITIONS TO AVOID |
|---|---|
| May Occur ___ Will Not Occur **X** | Not determined |

### SECTION 7 – SPILL OR LEAK PROCEDURES

**STEPS TO BE TAKEN IN CASE MATERIAL IS LEAKED OR SPILLED**

Clean up spills with an absorbent material. Dispose of this material in a biohazard container. Wipe down the area of the spill with 10% bleach. All cleaning items and gloves should be discarded into a biohazardous container.

**ECOLOGICAL INFORMATION**

No environmental hazard is anticipated provided the materials are handled and disposed of with due care and attention.

**WASTE DISPOSAL METHOD**

Dispose in a biohazardous waste container for collection by waste contractor. Additional items that have come into contact with the controls (e.g., pipette tips, test cartridges) should also be disposed of in a biohazardous waste container.

### SECTION 8 – PERSONAL PROTECTION INFORMATION

**RESPIRATORY PROTECTION**

Not required under normal and intended uses

**VENTILATION**

Not applicable

| PROTECTIVE GLOVES | EYE PROTECTION |
|---|---|
| Wear protective gloves during reconstitution and testing | Not required |

**OTHER PROTECTIVE CLOTHING OR EQUIPMENT**

Wear laboratory coat for personal protection

### SECTION 9 – SPECIAL PRECAUTIONS

**PRECAUTIONS TO BE TAKEN IN HANDLING & STORING**

Controls should be transported unopened at 36–46ºF (2–8ºC).
Store unopened controls at 2–8ºC. Expiration date is shown on the outside of the box. After reconstitution the controls are stable for up to five days at 36–46ºF (2–8ºC).

**OTHER PRECAUTIONS**

All donors have been screened by Food and Drug Administration USA (FDA) approved tests and found to be negative for HbsAg, HCA and HIV Antibodies. However as no testing can claim total absence of infections agents they should be handled as though they are capable of transmitting an infectious disease. Very slight risk of biological infection.

### NOTES

# MATERIAL SAFETY DATA SHEET

CHOLESTECH

**Cholestech GDX™ Optics Check Cartridge**

## SECTION 1 – IDENTITY

| NAME | | ADDRESS |
|---|---|---|
| Cholestech GDX™ System | | 3347 Investment Blvd., Hayward, CA 94545 |
| **TELEPHONE NUMBER** | **FOR ADDITIONAL INFORMATION CONTACT** | **DATE PREPARED** |
| 800-733-0404 | Technical Service | June 21, 2002 |
| **COMMON NAME (USED ON LABEL)** | | **CHEMICAL FAMILY** |
| Cholestech GDX Optics Check Cartridge | | Does not apply |
| **CHEMICAL NAME** | | **FORMULA** |
| Does not apply | | Does not apply |
| **TRADE NAME & SYNONYMS** | | |
| Cholestech GDX,™ Trademark of Cholestech Corporation | | |

## SECTION 2 – HAZARDOUS INGREDIENTS

| HAZARDOUS COMPONENT | CAS # | % (wt) | TLV | PEL |
|---|---|---|---|---|
| None | | | | |

PEL: Permissible Exposure Limit established by the Occupational Safety & Health Administration (OSHA).
TLV: Threshold Limit Value established by the American Conference of Governmental Industrial Hygienists, 1987–88.

## SECTION 3 – PHYSICAL DATA

| BOILING POINT | SPECIFIC GRAVITY | VAPOR PRESSURE |
|---|---|---|
| Not determined | ($H_2O=1$)<br>Not determined | (mm Hg)<br>Not determined |

| PERCENT VOLATILE BY VOLUME (%) | VAPOR DENSITY (AIR=1) | EVAPORATION DATE (_____- 1) |
|---|---|---|
| Not determined | Not determined | Not determined |

| SOLUBILITY IN WATER | REACTIVITY IN WATER |
|---|---|
| Insoluble | Not determined |

**APPEARANCE AND ODOR**
Colorless plastic housing with red/orange dye in 2 wells
Odor – none

## SECTION 4 – FIRE AND EXPLOSION DATA

| FLASH POINT | FLAMMABLE LIMITS IN AIR (% by VOLUME) |
|---|---|
| >212ºF (100ºC) | LOWER: Not determined UPPER: Not determined |
| **EXTINGUISHING MEDIA** | **AUTO IGNITION TEMPERATURE** |
| Foam, dry powder, carbon dioxide of vaporizing liquids Not determined | Not determined |

**UNUSUAL FIRE AND EXPLOSION HAZARDS**
Combustible

**SPECIAL FIRE-FIGHTING PROCEDURES**
None

## SECTION 5 – HEALTH INFORMATION

**PRIMARY ROUTES OF EXPOSURE**
Note: contact with the silicone elastomer can only be made if the unit is broken.
Skin, ingestion
The material is a solid. No contact with the eye is possible under normal circumstances.

**SIGNS AND SYMPTOMS OF EXPOSURE**
(1) ACUTE OVEREXPOSURE – None
(2) CHRONIC OVEREXPOSURE – None

**MEDICAL CONDITIONS GENERALLY AGGRAVATED BY EXPOSURE**
None

| CHEMICAL/COMPONENT LISTED AS CARCINOGEN OR POTENTIAL CARCINOGEN | NTP | IARC | OSHA |
|---|---|---|---|
| None | ___ Yes<br>___ No | ___ Yes<br>___ No | ___ Yes<br>___ No |

**OTHER EXPOSURE LIMITS**
None

**EMERGENCY & FIRST AID PROCEDURES**
Inhalation – not applicable
Skin contact – Wash off thoroughly with soap and water
Ingestion – Wash out mouth thoroughly with water

*Continued on next page.*

## MATERIAL SAFETY DATA SHEET CONTINUED

CHOLESTECH

### SECTION 6 – REACTIVITY DATA

| STABILITY | CONDITIONS TO AVOID |
|---|---|
| Unstable ___ Stable X | Not determined |

**INCOMPATIBILITY (MATERIALS TO AVOID)**
Not determined

**HAZARDOUS DECOMPOSITION PRODUCTS**
Not determined

| HAZARDOUS POLYMERIZATION | CONDITIONS TO AVOID |
|---|---|
| May Occur ___ Will Not Occur X | Not determined |

### SECTION 7 – SPILL OR LEAK PROCEDURES

**STEPS TO BE TAKEN IN CASE MATERIAL IS LEAKED OR SPILLED**
Contact with the silicone elastomer can only be made if the unit is broken. No environmental hazard is anticipated provided the materials are handled and disposed of with due care and attention.

**WASTE DISPOSAL METHOD**
Chemical residues are generally classified as special waste, and as such are covered by Federal, State or local laws.

### SECTION 8 – PERSONAL PROTECTION INFORMATION

**RESPIRATORY PROTECTION**
Not applicable

**VENTILATION**
Not applicable

| PROTECTIVE GLOVES | EYE PROTECTION |
|---|---|
| Required to protect product | Not required |

**OTHER PROTECTIVE CLOTHING OR EQUIPMENT**
Not required

### SECTION 9 – SPECIAL PRECAUTIONS

**PRECAUTIONS TO BE TAKEN IN HANDLING & STORING**
Store at room temperature in a box away from direct sunlight and moisture. No special transportation requirements. Product does not present any hazards during shipment.

**OTHER PRECAUTIONS**
No environmental hazard is anticipated provided the materials are handled and disposed of with due care and attention.

**NOTES**

# 8.0 **Proficiency Testing**

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# *Proficiency Testing*

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## 8.1 Overview of Proficiency Testing

Under CLIA ‘88, all laboratories conducting tests classified moderately complex and highly complex must participate in an approved proficiency testing (PT) program for each specialty they perform testing in.

The purpose of this section is to discuss the importance of proficiency testing and describe how proficiency testing is performed. When choosing the appropriate agency for your testing, it is important to ask the agency if it is certified by the Centers for Medicare & Medicaid Services (CMS) to comply with CLIA ’88 standard regulations.

### What Is Proficiency Testing?

Although analyzing quality control specimens provides an “internal” check on the quality of a laboratory’s results, proficiency testing serves as an “external” check. Outside agencies send “unknown” specimens to subscribing laboratories. The laboratory performs the required tests and returns the results to the agency. The data are analyzed and a summary report is sent to the laboratory indicating the laboratory’s performance.

### Why Is Proficiency Testing Necessary?

Proficiency testing assures the user of quality results and measures the performance of the test system and operators relative to other laboratories using the same test system or a reference method.

Testing may identify bias in a test system, which may not be apparent with an internal daily quality control program.

Proficiency testing may be necessary for compliance with state or federal law (e.g., CLIA ’88).

### How Does Proficiency Testing Work?

Proficiency testing is one aspect of a quality assurance program. The method works in conjunction with a daily internal quality control program. When properly controlled, it indicates the laboratory’s accuracy performance on the test system being evaluated.

A number of agencies offer proficiency testing surveys. The surveys vary by the analytes offered for testing, number of challenges per analyte, number of mailings per year, report format, sample preparation and result evaluation.

1. Surveys are offered for most routine tests performed.

2. Under CLIA ’88, proficiency testing is required three times per year, testing five samples each time for moderately complex and highly complex labs.

3. The specimen of choice for the Cholestech GDX System is a specimen of human whole blood with no stabilizers.

   In Section 8.2 of this manual, a list of agencies offering CMS-approved proficiency surveys is provided. These agencies are the ones Cholestech has evaluated and found to demonstrate acceptable performance on the Cholestech GDX. For testing other



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instruments in your laboratory, it is important to contact the manufacturer and request the names of agencies that run compatible surveys with no matrix interferences on these instruments or systems.

4. The survey samples are mailed to the participating laboratories according to a schedule set by the proficiency testing agency. Within the time limit set by the agency, the laboratory personnel perform the required tests on the survey specimens. *Only tests performed in the laboratory should be analyzed. Survey specimens are handled and analyzed using the same procedure as that for patient specimens.*

5. Results on the survey specimens are entered on a preprinted form, coded according to reagent-instrument method and returned to the proficiency testing agency.
   - After evaluation statistics have been calculated, a summary report of results is sent to all participating laboratories.
   - Laboratories may also request that a proficiency testing agency send a copy of its results to state or federal regulatory agencies.
   - In general, regulatory agencies require documented evidence of corrective action taken when survey results fall outside acceptable limits. The director of a point-of-care laboratory will review all proficiency testing results and document the review and responses to unacceptable results.
   - Cholestech Technical Service can provide assistance in troubleshooting proficiency testing failures.

## 8.2 Proficiency Testing Agencies

- The College of American Pathologists, EXCEL Program; 325 Waukegan Road, Northfield, IL 60093, Phone 800-323-4040.
- American Proficiency Institute; 1159 Business Park Drive, Traverse City, MI 49686, Phone 800-333-0958 / Fax 231-941-7287.
- Wisconsin State Laboratory of Hygiene, Proficiency Testing Program; 465 Henry Mall Room, Madison, WI 53706-1578, Phone 800-462-5261.

## 8.3 Reference(s) and Bibliography

1. National Committee for Clinical Laboratory Standards. *Physician's Office Laboratory Guidelines; Tentative Guidelines.* Villanova, Pa.: NCCLS; 1989. NCCLS publication POL1-T.

2. Howanitz PJ, Howanitz JH. *Laboratory Quality Assurance.* New York, N.Y.: McGraw-Hill Book Co; 1987.

3. How to avoid dangerous mistakes in a physician's office laboratory. Continuing Education Course No. 328, American Academy of Family Physicians Scientific Assembly; 1989.

# 9.0 **Troubleshooting**

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# *Troubleshooting*

## 9.1 Time / Sequence Errors

It is essential to follow the operational sequence without extensive delays between steps. The Analyzer measures time intervals between steps at appropriate points and will give an error message if the time interval exceeds the stated limits.

| ERROR CODE | TEST POSITION | TIME ALLOWED | EXPLANATION |
|---|---|---|---|
| 3 | Position 0 → Position 1 | 300 seconds (5 minutes) | A test cartridge is placed into the Analyzer and the prompt for turning to Position 1 is displayed. |
| 3 | Position 1 → Position 2 | 60 seconds (1 minute) | The Analyzer is prompting you to turn the test cartridge to Position 2. |
| 3 | Position 2 → Position 3 | 300 seconds (5 minutes) | The Analyzer is prompting you to turn the test cartridge to Position 3. |
| 3 | Between Positions | 10 seconds | A test cartridge is turned to a position halfway between any of the positions. |
| 5 | Position 1 | 300 seconds (5 minutes) | Prompt for pressing the enter button is ignored. Time allowed pouring sample and incubating. |
| 5 | Position 2 | 60 seconds (1 minute) | Prompt for pressing the enter button is ignored. Time allowed pouring buffer. |
| 6 | Position 1 | 30 seconds | After incubation, the allowed time to remix and pour the sample into the funnel. |
| 6 | Position 3 | 60 seconds (1 minute) | The solution (third tube) was not poured into the funnel in time. |

## 9.2 Analyzer / Test Errors

The Cholestech GDX Analyzer has been programmed to detect any Analyzer or test problems. An error message will appear on the display if any mistakes arise during the test.

Look at the following table to see the cause of the error message and the possible correction.

**In the event of technical difficulty or Analyzer failure, contact:**

**Cholestech Technical Service**
**800-733-0404**

| ERROR CODE | EXPLANATION | ACTION TO TAKE |
|---|---|---|
| **Err-1**<br>Test abandoned by the user<br><br>A test cartridge was placed in the reader and immediately removed again. | A test cartridge was placed in the reader and immediately removed again.<br>This error may be caused by a problem with the microswitches in the Analyzer. | Press the round enter button to start another test.<br>Check the Analyzer using an Optics Check Cartridge. Call Technical Service if message reappears. |
| **Err-2**<br>Test cartridge not present<br><br>Analyzer has failed to detect a cartridge. There may be a problem with the microswitches or the cartridge is damaged. | Damage to the Analyzer has caused microswitch failure.<br>Test cartridge is damaged.<br>Test cartridge was turned from Position 0 to Position 1 before the Analyzer prompt.<br><br>Error persists. | Check the Analyzer using an Optics Check Cartridge.<br>Retest using a new cartridge.<br>Repeat the test, making sure that all timed sequence steps are performed according to the manufacturer's instructions.<br>Call Technical Service. |
| **Err-3**<br>Cartridge not rotated in time<br><br>It is essential to follow the operational sequence without extensive delays between steps. The Analyzer measures time intervals between steps at appropriate points and will error if the interval is above certain limits. | A test cartridge is placed into the Analyzer and the prompt for turning to Position 1 is displayed. If the prompt is ignored for greater than 300 seconds, Error 3 is displayed.<br>If the test cartridge is at Position 1 and the prompt for turning to Position 2 is ignored for greater than 60 seconds, Error 3 is displayed.<br>If the test cartridge is at Position 2 and the prompt for turning to Position 3 is ignored for greater than 300 seconds, Error 3 is displayed.<br>A test cartridge is placed in the Analyzer and the prompt for turning to any of the positions is flashing. The cartridge is turned to a position halfway between and left for 10 seconds. Error 3 is displayed.<br>The error may be caused by a problem with the microswitches in the Analyzer. | Run the Optics Check Cartridge to check that there are no problems with the Analyzer. Repeat the test with a new test cartridge, making sure that all timed sequence steps are performed correctly according to the manufacturer's instructions. If the error message persists, call Technical Service.<br><br>Run the Optics Check Cartridge to check that there are no problems with the Analyzer. If the error message persists, call Technical Service. |

| ERROR CODE | EXPLANATION | ACTION TO TAKE |
|---|---|---|
| **Err-4**<br>Cartridge in the wrong position<br><br>The cartridge has been moved out of sequence (i.e. moved when not prompted). | A test cartridge is turned between Positions 1 and 2 before being prompted by the Analyzer.<br>A test cartridge is turned between Positions 3 and 0 before being prompted by the Analyzer. | Complete the rotation of the cartridge (clockwise) to the beginning position. Take the cartridge out and push the enter button. The screen will then indicate for a new cartridge.<br><br>Repeat the test with a new test cartridge, making sure that all timed sequence steps are performed according to the manufacturer's instructions. |
| **Err-5**<br>Sequence time-out<br><br>It is essential to follow the operational sequence without delays between steps. The Analyzer measures time intervals between steps at appropriate points and will error if the interval is above certain limits. | A test cartridge is placed in the Analyzer and advanced to Position 1. If the prompt for pressing the enter button is ignored for more than 300 seconds, Error 5 will be displayed.<br>A test cartridge is advanced to Position 2. If the prompt for pressing the enter button is ignored for more than 60 seconds, Error 5 will be displayed.<br>Analyzer failure. | Repeat the test with a new test cartridge, making sure that all timed sequence steps are performed according to the manufacturer's instructions. If the error message persists, call Technical Service.<br><br>Call Technical Service. |
| **Err-6**<br>Addition of sample not detected<br><br>The Analyzer has failed to detect a meniscus flow within the defined time limit. It is essential to follow the operational sequence without extensive delays between steps. | The test procedure has been followed up to the Analyzer prompt for the remixing of blood in the sample tube and for it to be poured into the funnel. If the blood sample is not poured into the funnel, after 30 seconds the liquid will not be detected and Error 6 will be displayed.<br>A test cartridge has been run up to the stage of the Analyzer prompt for the pouring of the contents of the third tube into the funnel. After 60 seconds it cannot be detected and Error 6 will be displayed. | Repeat the test with a new test cartridge, making sure that all timed sequence steps are performed correctly according to the manufacturer's instructions. |
| **Err-7**<br>Enter button depressed too early<br><br>It is essential to follow the procedure according to the instruction manual. The Analyzer measures time intervals between steps and will error if the interval is so short that the user could not have performed the particular operation. | During the normal testing procedure, the display prompts the user to take the blood sample tube and press the enter button to start the incubation period. Error 7 will be displayed when the enter button is pressed immediately after the prompt message is displayed.<br>If the above has been performed, but the time elapsed before the enter button is pressed is between 1 and 9 seconds, Error 7 will be displayed. If the enter button is pressed after 10 seconds, no error message will be displayed.<br>A test cartridge has been run up to the Analyzer prompt for the enter button to be pressed after the contents of the second tube are poured down the funnel. Error 7 will be displayed if the enter button is pressed immediately or within 4 seconds. | Check the Analyzer using an Optics Check Cartridge. Retest using a new cartridge and ensuring the timing sequence is correct. |



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| ERROR CODE | EXPLANATION | ACTION TO TAKE |
|---|---|---|
| **Err-8**<br>Position 1 blank reading out of range<br><br>The Analyzer has detected unacceptable through-beam intensity. This may result from a dirty or damaged cartridge or an Analyzer failure. | The test cartridge has been damaged. | Run the Optics Check Cartridge. If the Optics Check Cartridge fails, remove it from the Analyzer and check that the cartridge is not scratched, dirty or covered in fingerprints. If the Optics Check Cartridge looks dirty, clean with lint-free cloth and retest. If the Optics Check Cartridge is damaged or scratched, contact your distributor for a replacement. |
| | The Analyzer has been damaged. | Power off the Analyzer and power it back on again. Try running the Optics Check Cartridge again. If the error message persists, call Technical Service. |
| | Dirt on/in cartridge. | Repeat the test using a new test cartridge. |
| | Dirt or obstruction in Analyzer. | Check the cartridge well and optical window for dirt. |
| **Err-9**<br>Position 3 blank reading out of range<br><br>The Analyzer has detected an unacceptable signal. This may result from a dirty or damaged cartridge or an Analyzer failure. To eliminate Analyzer failure as the cause, run the Optics Check Cartridge. | The test cartridge has been damaged. | Run the Optics Check Cartridge. If the Optics Check Cartridge fails, remove it from the Analyzer and check that the cartridge is not scratched, dirty or covered in fingerprints. If the Optics Check Cartridge looks dirty, clean with lint-free cloth and retest. If the Optics Check Cartridge is damaged or scratched, contact your distributor for a replacement. |
| | The Analyzer has been damaged. | Power off the Analyzer and power it back on again. Try running the Optics Check Cartridge again. If the error message persists, call Technical Service. |
| | Dirt on/in cartridge. | Repeat the test using a new test cartridge. |
| | Dirt or obstruction in Analyzer. | Check the cartridge well and optical window for dirt. |
| **Err-10**<br>This may be caused by an insufficient blood sample being taken. | A faulty blood collection pipette and/or not enough blood added to the first tube. | Repeat the test using a new test cartridge and a new blood collection pipette. |
| | User error; the user is unfamiliar with the blood collection pipette and has underfilled the pipette. | Check the blood sampling technique with user instructions. If necessary, practice using the pipette before running a test. |
| **Err-11**<br>Absorbance 1 calculation too high<br><br>This may be caused by too much blood being taken or, in rare cases, a hematocrit value that is very high or a combination of the two. | A faulty blood collection pipette is used and/or too much blood added to the sample tube. | Repeat the test using a new test cartridge and a new blood collection pipette. |
| | User error; the user is unfamiliar with the blood collection pipette and has overfilled the pipette. | Check blood sampling technique with user instructions. If necessary, practice using the pipette before running a test. |
| | A blood sample has a high hematocrit. | Establish whether the patient has a high hematocrit value. |
| **Err-12**<br>Absorbance 3 calculation too low<br><br>This may be caused by an insufficient blood sample being taken initially. Repeat the test, taking care to fill the blood collection pipette correctly. | A faulty blood collection pipette is used and not enough blood is added to sample tube. | Repeat the test using a new test cartridge and a new blood collection pipette. |
| | User error; the user is unfamiliar with the blood collection pipette and has underfilled the pipette. | Check blood sampling technique with user instructions. If necessary, practice using the pipette before running a test. |
| | A faulty cartridge. | Repeat the test with a new test cartridge. |

| ERROR CODE | EXPLANATION | ACTION TO TAKE |
|---|---|---|
| **Err-13**<br>Absorbance 3 calculation too high<br><br>Values above a certain level of glycation are extremely rare. Repeat the test. | User error. The user is unfamiliar with the blood collection pipette and has overfilled the pipette. | Check blood sampling technique with user instructions. If necessary, practice using the pipette before running a test. |
| | Analyzer error. In rare circumstances, this may be an Analyzer problem. | Power Analyzer off, power back on again and repeat the test using an Optics Check Cartridge. If the Optics Check cartridge gives the correct result, repeat the test using a new test cartridge. |
| | Contamination of solution in third tube. | Repeat the test using a new test cartridge. If error message persists, record lot number and contact Technical Service. |
| **Err-14**<br>Reading not stable<br><br>This may be caused by contamination of the fluid with extraneous fibers or the Analyzer is not physically stable. | Analyzer malfunction. | Check the Analyzer using an Optics Check Cartridge. Check that the bench/table is not vibrating or moving due to other laboratory equipment. |
| | Test cartridge malfunction. | If the Analyzer is working correctly, repeat the test with a new cartridge. If the error message persists, contact Technical Service. |
| **Err-15**<br>Reading not completed in time<br><br>The final reading must be obtained within 10 seconds. If a stable signal is not achieved, contamination is likely. | Analyzer malfunction. | Power Analyzer off, power back on again and repeat the test using an Optics Check Cartridge. If the Optics Check cartridge gives the correct result, repeat the test using a new test cartridge. |
| | Test cartridge malfunction. Contamination of solutions in the tubes would prevent a stable signal from being achieved. | Repeat the test using a new test cartridge. If error message persists, record lot number and contact Technical Service. |
| **Err-16**<br>Blank reading not completed in time<br><br>The optical system is not stable. Repeat the test. | Analyzer malfunction.<br><br>The Analyzer has experienced a rapid change in temperature from very cold to room temperature. This may happen when left in a cold car overnight and taken into a warm room. | Allow the Analyzer to warm up to room temperature. Power Analyzer off, power back on again and repeat the test using an Optics Check Cartridge. If the Optics Check cartridge gives the correct result, repeat the test using a new test cartridge. |
| | Test cartridge malfunction, although this is unlikely. | Repeat the test with new test cartridge. |
| **Err-17**<br>Blue LED failed/Test cartridge not removed | A test cartridge or Optics Check Cartridge has been left in the Analyzer while the Analyzer is connected to the power supply but not in use. | Remove the cartridge, turn off the power supply and disconnect the Analyzer. Reconnect the Analyzer, allow to warm up and insert an Optics Check Cartridge. |
| | LED/photodiode has failed. | Call Technical Service. |
| **Err-18**<br>Air blank 1 low<br><br>The Analyzer has detected an unacceptable signal intensity. | The test cartridge used may be damaged. | Remove the cartridge, turn off the power supply and disconnect the Analyzer. Reconnect the Analyzer, allow to warm up and insert an Optics Check Cartridge. |

*Continued on next page.*



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| ERROR CODE | EXPLANATION | ACTION TO TAKE |
|---|---|---|
| **Err-18** *(continued)* | A cartridge has been left "resting" in the Analyzer. | Remove the cartridge, turn off the power supply and disconnect the Analyzer. Reconnect the analyzer, allow to warm up and insert an Optics Check Cartridge. |
| | Analyzer failure. | Power off the Analyzer and power it back on again. Try running the Optics Check Cartridge again. If the error message persists, call Technical Service. |
| **Err-19**<br>Air blank 2 low<br><br>The Analyzer has detected an unacceptable signal intensity. | The test cartridge used may be damaged. | Remove the cartridge, turn off the power supply and disconnect the Analyzer. Reconnect the Analyzer, allow to warm up and insert an Optics Check Cartridge. |
| | Analyzer failure. | Power off the Analyzer and power it back on again. Try running the Optics Check Cartridge again. If the error message persists, call Technical Service. |
| **Err-20**<br>Air blank 3 low<br><br>The Analyzer has detected unacceptable through-beam intensity. | The test cartridge used may be damaged. | Remove the cartridge, turn off the power supply and disconnect the Analyzer. Reconnect the Analyzer, allow to warm up and insert an Optics Check Cartridge. |
| | Analyzer failure. | Power off the Analyzer and power it back on again. Try running the Optics Check Cartridge again. If the error message persists, call Technical Service. |
| **Err-21**<br>Air blank 1 high<br><br>The Analyzer has detected unacceptable through-beam intensity. | The test cartridge used may be damaged. | Remove the cartridge, turn off the power supply and disconnect the Analyzer. Reconnect the Analyzer, allow to warm up and insert an Optics Check Cartridge. |
| | Analyzer failure. | Power off the Analyzer and power it back on again. Try running the Optics Check Cartridge again. If the error message persists, call Technical Service. |
| **Err-22**<br>Air blank 2 high<br><br>The Analyzer has detected unacceptable through-beam intensity. | The test cartridge used may be damaged. | Check the test cartridge for the presence of a solid white pad. If this pad is missing, record the lot number for the box and call Technical Service. |
| | Analyzer failure. | Power off the Analyzer and power it back on again. Try running the Optics Check Cartridge again. If the error message persists, call Technical Service. |
| **Err-23**<br>Air blank 3 high<br><br>The Analyzer has detected unacceptable through-beam intensity. | The test cartridge used may be damaged. | Remove the cartridge, turn off the power supply and disconnect the Analyzer. Reconnect the Analyzer, allow to warm up and insert an Optics Check Cartridge. |

*Continued on next page.*

| ERROR CODE | EXPLANATION | ACTION TO TAKE |
|---|---|---|
| **Err-23** *(continued)* | Analyzer failure. | Power off the Analyzer and power it back on again. Try running the Optics Check Cartridge again. If the error message persists, call Technical Service. |
| **Err-24**<br>Supply voltage out of range<br><br>The Analyzer must be run with 11.4–12.6 volts DC. | Transformer malfunction. | Call Technical Service. |
| **Err-25**<br>Stirrer not responding<br><br>The system detects the current drawn when operating the electromagnet. | If there is an Analyzer failure, there will be no voltage drop, therefore the mixing paddle in the cartridge will not work. | Power off the Analyzer and power it back on again. Try running the Optics Check Cartridge again. If the error message persists, call Technical Service. |
| **Err-26**<br>Warm-up cycle not completed in time | The Analyzer has been removed from a cold environment and not given time to warm up to ambient temperature. This will result in condensation forming on the Analyzer optics. | Disconnect the Analyzer. Leave the Analyzer in a warm, dry place for at least one hour. Check the optics windows in the testing well for dust, fluff or other obstruction. Reconnect the power supply and run an Optics Check Cartridge. If the result is within specification, run a test cartridge. If the error message persists, call Technical Service. |
| **Err-27**<br>Programmed Analyzer shutdown<br><br>The Analyzer has reached the limit of 9,999 test operations. | The Analyzer is programmed to perform 9,999 readings. | This has been programmed into the Analyzer so that there will never be two results with the same ID code generated on the same Analyzer. |

# 10.0 **Glossary of Terms**

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# *Glossary of Terms*

**Acceptable Control Range** – range of results that indicate adequate performance when analyzing a control sample. The range is shown in the control's assay sheet.

**Accuracy** – correctness; freedom from error. The accuracy of results can be measured by comparing them with those from another laboratory (this is "*relative accuracy*").

**Additive** – chemical added to a blood collection tube, usually to prevent the blood from clotting (anticoagulant).

**Aerosol** – fine mist that solid or liquid particles are dispersed in.

**Agglutination** – clumping together of antigen-bearing cells, bacteria, or particles in the presence of specific antibodies. Also called "*clumping*."

**Aliquot** – small portion of a measured volume of a substance taken as a sample representing the whole.

**Analysis** – laboratory procedure that enables measurement of the amount of an analyte in a specimen.

**Analyte** – substance or constituent being measured (*e.g.,* cholesterol, triglycerides, glucose).

**Antibody** – substance formed in the body in response to a foreign substance (an *antigen*) and that interacts only with that substance.

**Anticoagulant** – chemical used to prevent blood from clotting.

**Antigen** – any substance that, injected into an organism, causes the development of antibodies.

**Antiserum** – serum that contains antibodies.

**Aseptic** – free from infection or septic material; sterile.

**Assay** – measurement of the amount of an analyte in a specimen; a test.

**Autoclave** – instrument that sterilizes material by subjecting it to steam under pressure.

**Bias (inaccuracy)** – measure of the departure from accuracy. A numerical difference between the mean of a set of replicate measurements and the true value of the sample.

**Calibrated** – (of a measuring device, *e.g.,* a pipette) graduated into appropriate units.

**Calibration** – taking readings from an instrument or other measuring device and relating them to known concentrations of an analyte or true value.

**Calibrator** – material, solution, or freeze-dried preparation used in calibration. The concentration of the analytes in a calibrator is known to be within a particular range. Calibrators may be a primary or a secondary standard.

**Capillary** – any one of the small vessels that form a network throughout the body for the interchange of substances between the blood and tissue fluid.

**Capillary (capillary action)** – attraction between a liquid and a solid that causes the liquid to rise, as for example, into a capillary tube.

**Centrifuge** – instrument that separates the lighter portions of a solution, mixture, or suspension from the heavier portions by centrifugal force.

**Coagulation** – how various coagulation factors in the blood interact to form a clot.

**Coefficient of Variation** – statistical measure of the ratio of the standard deviation of a series of measurements to the mean of the measurements. Expressed as a percentage, the coefficient of variation (CV) shows the precision of measurements.

**Colorimeter** – measurement and analysis of color by comparison with a standard in terms of brightness, hue, or purity.

**Contaminant** – microorganism, chemical, or other material that makes something impure by contact or mixture with it.

**Control** – material, solution, lyophilized preparation, or pool of collected serum designed to be used in the process of quality control. The concentrations of the analytes of the interest in the control material are known within limits ascertained during its preparation, and confirmed in use.

**Data** – numerical or quantitative results of a test that conclusions are made from.

**Diagnostic Test** – laboratory test or measurement that helps determine the cause or nature of a disease. Laboratory tests are often called "*in vitro* diagnostic tests."

**Diluent** – liquid (usually distilled water) used to reconstitute a freeze-dried control or reagent.

**Dilution** – mixing of a diluent and a calibrator, or control, or patient sample. A serial dilution is the progressive dilution of a substance in a series of tubes in predetermined ratios.

**ELISA** – enzyme-linked immunosorbent assay; a diagnostic test used to detect either antigens or antibodies in a patient's specimen.

**Enzyme** – compound produced in a cell and capable of greatly increasing the rate of a chemical reaction.

**Erythrocyte** – red blood cell, one of the elements in peripheral blood.

**Etiologic Agent** – agent that causes disease.

**False Negative (Result)** – negative test result for a patient who is positive for the condition or constituent in question.

**False Positive (Result)** – positive test result for a patient who is negative for the constituent or condition in question.

**Glycolysis** – lowering of glucose concentration in a blood sample by the action of enzymes in the red blood cells.

**Gravimetry** – measurement of a substance by determining its weight or specific gravity.

**Hematoma** – mass of blood, usually clotted, under the skin in an organ, space, or tissue caused by a break in the wall of a blood vessel.

**Hematocrit** – (also called *packed cell volume*) volume percentage of erythrocytes (red blood cells) in whole blood.

**Hemolysis** – (adjective *hemolytic*) breakdown of red blood cells in serum or plasma, freeing the hemoglobin from the cells. When this happens, the serum or plasma becomes reddish. Hemolysis interferes with some laboratory tests. *Beta hemolysis* is the production of a clear zone surrounding a bacterial colony on blood-agar medium, which is characteristic of certain pathogenic bacteria such as Group A *Streptococcus*.

**Icterus** – (adjective icteric) condition in which there is too much bilirubin in the blood; jaundice. An icteric serum sample looks dark yellow (it may even look greenish). An icteric sample may produce erroneous test results.

**Immunoassay** – diagnostic test that uses a specific antibody or antigen to detect the presence of an analyte.

**Inaccuracy** – see *Bias.*

**In Control** – in a testing procedure when the results from a control sample or series of control samples are within the acceptable control range.

**Infectious Agent** – any microorganism that can invade body tissue and multiply, causing infection.

***In Vitro*** – Latin for "in glass," used to describe diagnostic tests that analyze processes occuring inside the body (*in vivo*) from samples of body fluids in glass (test tubes) or other controlled artificial environments.

**Levey-Jennings Chart** – quality control chart; a graph or table that shows results of control tests over a period of time; used in a quality control program.

**Linearity** – measure of the range (the *linear range*) of concentration of an analyte over which a measure or test produces consistent (*i.e.,* linear, straight line) and accurate results.

**Lipemia** – (adjective *lipemic*) condition of too much fat or lipids in the blood. A lipemic serum sample looks milky and turbid, and may produce erroneous results.

**Lyophilized** – freeze-dried; a lyophilized calibrator, control, or reagent has been specially dried to make its analytes more stable. It must be refrigerated to maintain its stability, and is reconstituted by adding an appropriate diluent.

**Matrix** – physical and chemical properties that describe a fluid. Often used to describe the effect of differences seen when lyophilized (freeze-dried) samples, such as control material, behave differently than patient specimens when analyzed.

**Mean** – average of the numerical results obtained from a series of analyses.

**Method** – analytical method; the instructions including procedures, material, equipment, and everything else needed for an analyst to perform an analysis.

**Normal Values (Expected Values, Reference Values)** – range of values established for each analyte, which includes the results expected when performing a test on a healthy person.

**Out of Control** – in a testing procedure when the results from a control sample are outside the acceptable control range.

**Pathogen** – (adjective *pathogenic*) microorganism that causes a disease.

**Phlebotomy** – puncture of a vein to collect blood. A *phlebotomist* collects blood by venipuncture (venous blood).

**Photometry** – measurement or analysis of light emitted by a substance. *Reflectance photometry* is the principle used in most instruments that read dry reagent strips.

**Pipette** – glass or transparent plastic tube used to measure small quantities of liquid. A *volumetric pipette* is an extremely accurate, single-line pipette used to reconstitute calibrators and controls.

**Plasma** – liquid part of blood after it has been mixed with an anticoagulant and spun down in a centrifuge.

**Precision (reproducibility)** – measure of the closeness of the results obtained when analyzing the same sample more than once; the measure of agreement between replicate measurements.

**Procedure Manual** – laboratory manual that contains the methods, materials, and other information needed to do a test.

**Product Insert** – informational material that comes with instruments, reagents, and other laboratory products giving instructions for the use of the product and other information required of the manufacturer by the U.S. Food and Drug Administration.

**Proficiency Samples** – analytes of unknown concentration that are sent to laboratories participating in proficiency testing programs.

**Proficiency Testing** – program in which samples are sent to a group of laboratories for analysis. The results are tabulated by the program's sponsor, and a participating laboratory can compare its results with those of other laboratories that use the same method.

**Protocol** – standard set of procedures for performing a procedure, such as a test or an evaluation.

**Quality Assurance** – comprehensive set of policies, procedures, and practices necessary to make sure that the laboratory's results are reliable. QA includes record keeping, calibration, and maintenance of equipment, quality control, proficiency testing, and training.

**Quality Control** – set of laboratory procedures designed to ensure that the test method is working properly and that the results meet the diagnostic needs of the physician. QC includes testing control samples, charting the results, and analyzing them statistically.

**Quantitative** – applied to tests that give results expressing the numerical amount of an analyte in a specimen. This is in contrast to qualitative tests that detect whether a particular analyte, constituent, or condition is present.

**Reactivity** – ability of a reagent to produce its proper chemical reaction. Reagents can lose their reactivity if they are misused, mishandled, or are too old.

**Reagent** – substance that produces a chemical reaction in a sample that allows an analyte to be detected and measured.

**Reconstitute** – to add a diluent to a freeze-dried calibrator, control, or reagent.

**Reference Interval** – see *Normal Values.*

**Replicate** – to repeat an experiment and/or analysis to check the accuracy of the results. Each repeat is a replicate (pronounced *rep*-li-kit) test or measurement.

**Reproducibility** – see *Precision*.

**Result** – value obtained by analysis for a particular analyte in a particular sample.

**Run (analytical run)** – group of measurements by a particular method over a period of time during which the accuracy and precision of the method are expected to be stable.

**Sample** – part of a specimen used for an analysis.

**Sensitivity** – ability of a test to give a positive result for patients who have the disease or condition they are tested for; measured as the ratio of positive tests to the total number of tests in those who have the disease; expressed as a percentage.

**Serum** – liquid part of the blood after it has coagulated and then been spun down in a centrifuge.

**Specificity** – ability of a test to give a negative result for patients who do not have the disease or condition they are tested for; measured as the ratio of negative tests to the total number of tests in those who do not have the disease or condition; expressed as a percentage.

**Specimen** – portion of body fluid (e.g., blood or urine) collected from the patient.

**Split-Sample Testing** – dividing a sample in half, and testing half in your laboratory and having the other half tested in another laboratory, and then comparing the results. This is a technique for testing accuracy.

**Stability** – ability of a specimen, reagent, or control to maintain a constant concentration of the analyte. Reagents and controls must be handled and stored properly and used before their expiration dates to maintain their stability. Specimens must be collected, handled, and processed properly.

**Standard, Primary** – reference material of fixed and known chemical composition and capable of being prepared in essentially pure form. Also: any certified reference material generally accepted or officially recognized as the unique standard for the assay regardless of its level of purity of analyte content.

**Standard, Secondary** – reference material, the analyte concentration of which has been ascertained by reference to a primary standard.

**Standard Deviation** – statistical measurement of the degree of variation from the mean of a series of measurements. It is a measure of precision or reproducibility.

**Test** – procedure for detecting the presence or amount of an analyte.

**Titer** – quantity of a substance required to produce a reaction with a particular amount of another substance. The amount of one substance required to correspond with a particular amount of another substance. *Agglutination titer* is the highest dilution of a serum that causes clumping of particulate antigens.

**Throughput** – applied to analytical instruments specifying the number of tests that can be performed in a given time.

**Toxicology** – study of the origin, nature, and effects of poison. Toxicological analyses are used to detect the amount of a substance that can be poisonous at a particular concentration.

**Turbidity** – (adjective *turbid*) cloudiness; distribution of a substance in a solution, making it unclear or cloudy.

**Value** – number, in units of the method, obtained for an analyte in a particular sample. See *Result*.

**Venipuncture** – procedure for collecting a blood sample from a vein (“venous blood”).

**Whole Blood** – blood mixed with an anticoagulant but not spun down in a centrifuge.

## 10.1 Reference(s) and Bibliography

1. National Committee for Clinical Laboratory Standards. *Physician’s Office Laboratory Procedure Manual; Tentative Guideline*. Villanova, Pa.: NCCLS; 1989. NCCLS publication POL2-T, Vol. 12, No. 5.

# 11.0 **Master Forms**

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# A1C RESULT LOG

Cholestech GDX Serial No.

Test Cartridge Lot No. Expiration Date

Optics Check Cartridge Lot No. Expiration Date Range

Control Lot No. Expiration Date Level 1 Range

Level 2 Range

| SAMPLE ID NO. | DATE | IDENTIFIER | PATIENT RESULTS | OPTICS CHECK | LEVEL 1 QC | LEVEL 2 QC | INITIALS |
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# TEMPERATURE CHART

YEAR

Record the temperature and initial the space provided. One sheet should be used per room, refrigerator, or freezer as *your* procedures dictate.

**Site ID** **Acceptable Temperature Range**

| | JAN | FEB | MARCH | APRIL | MAY | JUNE | JULY | AUG | SEPT | OCT | NOV | DEC |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
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| 31 | | | | | | | | | | | | |

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# INSTRUMENT HISTORY RECORD

Cholestech GDX™

## GENERAL INFORMATION

Instrument

Model No. | Serial No.

Date Purchased | Cost

Manufacturer

Address | City | State | Zip

Telephone | Contact Person

Distributor

Address | City | State | Zip

Telephone | Contact Person

Warranty | Contact Person

Notes:

Technical Service Representative | Telephone

## SERVICE RECORD

| Date | Comments |
|---|---|
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# INFORMATION AND SERVICE LOG

Cholestech GDX™

Instrument Serial No. Purchase Date Warranty Expires:

Customer Service Representative Phone No.

Technical Service Representative Phone No.

Sales Representative Phone No.

| DATE | PROBLEM | ACTION TAKEN | OPERATOR |
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# INITIAL SETUP CHECKLIST

Cholestech GDX™

**Cholestech GDX Serial No.** **Date of Setup**

**Name of Lab Person Performing Initial Setup**

**Signature Approval by Laboratory Director**

| FACILITY SPECIFICATIONS | OPERATOR | DATE |
|---|---|---|
| 1. Room temperature: 63–86°F (17–30°C) | | |
| 2. Stable work surface free from vibrations | | |
| 3. Isolation from direct heat and light sources (e.g., sunlight, ovens, room heater, etc.) | | |
| 4. A grounded wall outlet supplying 100 to 240 VAC with the appropriate power supply, which will not be interrupted during use. | | |
| **INSTALLATION** | | |
| 1. Verify that the wall outlet corresponds to the voltage requirements of the power supply. | | |
| 2. Connect the power plug to the power supply both to the inlet on the back of the instrument. | | |
| 3. Plug the power supply into the wall socket. | | |
| 4. The Analyzer will run through a check stage. All the red positional indicator lights on the Analyzer will flash, the beep will sound, and the display will show all icons and characters momentarily. | | |
| 5. A number will appear on the display. This is the version of software in the Analyzer, for example 2.06. | | |
| 6. The Hourglass icon will flash to tell you to wait. The maximum time required for warm-up is 10 minutes. | | |
| 7. The Insert and Cartridge icons will flash, when the Analyzer is ready for use. The “right” and “left” arrows will be solid. | | |
| 8. You can now use the Analyzer to run an Optics Check Cartridge or an A1C Test Cartridge. | | |
| NOTES | | |

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# EQUIPMENT MAINTENANCE / CLEANING LOG

Cholestech GDX™

| INSTRUMENT NAME | | | | | MAINTENANCE NOTES (problems reported, dates, solutions) |
|---|---|---|---|---|---|
| Serial No. | Quarterly Cleaning Schedule Dates | | | | |
| | | | | | |
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# INSTRUMENTS IN-USE RECORD

Cholestech GDX™

| INSTRUMENT/ MODEL | SERIAL NUMBER | MANUFACTURER | DATE INSTALLED | OPERATOR |
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# PATIENT RESULT LABEL LOG

Cholestech GDX™

Cholestech GDX Serial No. | Operator

Cartridge Lot No. | Expiration Date

| | | |
|---|---|---|
| Place Label Here | Place Label Here | Place Label Here |
| Place Label Here | Place Label Here | Place Label Here |
| Place Label Here | Place Label Here | Place Label Here |

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# QUALITY ASSURANCE RECORD

Cholestech GDX™

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| DATE | Control Level 1 Lot No. | | | | | Expiration Date | | |
| OPERATOR | Control Level 2 Lot No. | | | | | Expiration Date | | |
| | Cartridge Lot No. | | | | | Expiration Date | | |
| ROOM TEMP | | | | | | | | |
| REFRIG TEMP | RANGE | A1C | | Results | A1C | Accept | Reject | |
| | Level 1 | - | | Level 1 | - | | | |
| CHOLESTECH GDX SERIAL NO. | Level 2 | - | | Level 2 | - | | | |
| | OPTICS CHECK | | | | | Accept | Reject | |
| OPTICS CHECK LOT NO. | Result | | | | | | | |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| DATE | Control Level 1 Lot No. | | | | | Expiration Date | | |
| OPERATOR | Control Level 2 Lot No. | | | | | Expiration Date | | |
| | Cartridge Lot No. | | | | | Expiration Date | | |
| ROOM TEMP | | | | | | | | |
| REFRIG TEMP | RANGE | A1C | | Results | A1C | Accept | Reject | |
| | Level 1 | - | | Level 1 | - | | | |
| CHOLESTECH GDX SERIAL NO. | Level 2 | - | | Level 2 | - | | | |
| | OPTICS CHECK | | | | | Accept | Reject | |
| OPTICS CHECK LOT NO. | Result | | | | | | | |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| DATE | Control Level 1 Lot No. | | | | | Expiration Date | | |
| OPERATOR | Control Level 2 Lot No. | | | | | Expiration Date | | |
| | Cartridge Lot No. | | | | | Expiration Date | | |
| ROOM TEMP | | | | | | | | |
| REFRIG TEMP | RANGE | A1C | | Results | A1C | Accept | Reject | |
| | Level 1 | - | | Level 1 | - | | | |
| CHOLESTECH GDX SERIAL NO. | Level 2 | - | | Level 2 | - | | | |
| | OPTICS CHECK | | | | | Accept | Reject | |
| OPTICS CHECK LOT NO. | Result | | | | | | | |

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# CONTROL RANGE CALCULATION FORM

Cholestech GDX™

**Control Name** | **Lot No.** | **Analyte**

**Cartridge Lot No.** | **Cholestech GDX Serial No.**

☐ **Accept** ☐ **Reject** | **Director Approval** | **Approval Date**

| 1 | 2 | 3 | 4 | 5 | 6 |
|---|---|---|---|---|---|
| **No.** | **Date** | **Init.** | **Result** | **Result – $\bar{X}$** | **(Result – $\bar{X}$)²** |
| 1 | | | | | |
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| 18 | | | | | |
| 19 | | | | | |
| 20 | | | | | |
| **SUM (∑)** | | | | | |

NOTES

1. Record the date in Column 2 and the initials in Column 3.
2. Record the results of the quality control material in Column 4 – RESULT.
3. Calculate the MEAN ($\bar{X}$): Add the values (Column 4) in the RESULT Column then divide by the number of results (n):

$$\text{MEAN } (\bar{X}) = \frac{\Sigma \text{ Results}}{n}$$

4. Calculate the difference between each RESULT and the MEAN ($\bar{X}$) and record in Column 5 (RESULT – $\bar{X}$).
5. Square each value in Column 5 and record in Column 6 (RESULT – $\bar{X}$)².
6. Add the values in Column 6.
7. Calculate the standard deviation (SD) using the formula:

( Divide the sum of the values calculated in Column 6 by the number of values minus 1. Take the square root of this number. )

$$SD = \sqrt{\frac{\Sigma (\text{Results} - \bar{X})^2}{n - 1}}$$

8. The control range is the MEAN ($\bar{X}$) ± 2SD, record above.

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# ACCURACY STUDY DATA

Operator

Analyte

Cholestech GDX Serial No.

Cartridge Lot No.

Cartridge Expiration Date

| | REFERENCE METHOD | | | CHOLESTECH GDX | | | |
|---|---|---|---|---|---|---|---|
| | Sample | Date | Reference Method | 1 | 2 | $\bar{X}$ | % Difference |
| 1 | | | | | | | |
| 2 | | | | | | | |
| 3 | | | | | | | |
| 4 | | | | | | | |
| 5 | | | | | | | |
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| 9 | | | | | | | |
| 10 | | | | | | | |

Acceptable Accuracy Range is ± ____ %

$$\% \text{ Difference} = \frac{\text{Cholestech GDX Result} - \text{Ref. Result}}{\text{Ref. Result}} \times 100$$

Test Disposition ☐ Accept ☐ Reject

Director Approval

Approval Date

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# PRECISION CALCULATION FORM (WITHIN-RUN)

Cholestech GDX™

**Date** **Operator** **Specimen Identification** **Analyte**

**Cartridge Lot No.** **Cholestech GDX Serial No.**

☐ **Accept** ☐ **Reject** **Director Approval** **Approval Date**

| 1 | 2 | 3 | 4 |
|---|---|---|---|
| **No.** | **Result** | **Result – $\bar{X}$** | **(Result – $\bar{X}$)²** |
| 1 | | | |
| 2 | | | |
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| 18 | | | |
| 19 | | | |
| 20 | | | |
| **SUM (∑)** | | | |

NOTES

**$\bar{X}$ =**

**SD =**

**%CV =**

1. Record the result of the quality control material in Column 2 – RESULT.

2. Calculate the MEAN ($\bar{X}$): Add the values (Column 2) in the RESULT Column then divide by the number of results (n):

$$\text{MEAN } (\bar{X}) = \frac{\Sigma \text{ Results}}{n}$$

3. Calculate the difference between each RESULT and the MEAN ($\bar{X}$) and record in Column 3 (RESULT – $\bar{X}$).

4. Square each value in Column 3 and record in Column 4 (RESULT – $\bar{X}$)².

5. Add the values in Column 4.

6. Calculate the Standard Deviation (SD) using the formula:

( Divide the sum of the values calculated in Column 4 by the number of values minus 1. Take the square root of this number. )

$$SD = \sqrt{\frac{\Sigma (\text{Results} - \bar{X})^2}{n - 1}}$$

7. To calculate the coefficient of variation (%CV), use the following formula:

$$\%CV = \frac{SD}{\bar{X}} \times 100$$

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# TRAINING CHECKLIST

Cholestech GDX™

**Name**

**Director Signature** **Date Approved**

| PREPARATION | BY | DATE |
|---|---|---|
| 1. Has read User Manual. | | |
| 2. Has read Procedure Manual. | | |
| 3. Has viewed Cholestech GDX Training CD-ROM. | | |
| 4. Has read Cholestech GDX package insert. | | |
| 5. Understands room temperature storage procedures for test cartridges. | | |
| 6. Has been properly trained in procedure for handling biohazardous waste. | | |
| **THE CHOLESTECH GDX ANALYZER** | | |
| 7. Correctly connects the Analyzer to the power supply. | | |
| 8. Correctly connects the Analyzer to the printer (if applicable). | | |
| 9. Understands and demonstrates Analyzer functions. | | |
| 10. Understands the meaning of all LCD display icons. | | |
| 11. Demonstrates how to clean Analyzer. | | |
| **QUALITY ASSURANCE** | | |
| 12. Correctly performs the optics check procedure. | | |
| 13. Correctly performs the quality control procedure. | | |
| 14. Understands what actions are to be taken if the quality control results are outside acceptable limits. | | |
| 15. Understands Proficiency Testing. | | |
| 16. Understands appropriate record keeping: QC, patient logs, temperature monitoring, etc. | | |
| **PERFORMING A TEST** | | |
| 17. Properly prepares supplies for patient testing: alcohol swabs; gauze; lancets; MicoSafe™ Pipette; latex gloves; biohazardous waste container. | | |
| 18. Explains the procedure to the patient. | | |
| 19. Handles cartridge properly. | | |
| 20. Performs fingerstick using correct techniques. | | |
| 21. Performs test properly. | | |
| 22. Records results. | | |

NOTES

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# Certificate of Training

## for Fingerstick Blood Collection

I, Dr. _____, certify that _____

possesses the necessary skills and competencies to perform skin puncture for fingerstick blood collection.

This person has properly demonstrated to me fingerstick blood collection in accordance with currently accepted laboratory standards and protocols. Proper knowledge of the disposal of biohazardous material and industrial safety has been observed and comprehended for subsequent health events.

Authorization herein is limited to any nondiagnostic health program for general health assessment and does not include venipuncture, arterial puncture or any other procedure for obtaining a blood specimen.

Date _____

Physician's Name _____

DEA No. _____

Cholestech GDX™

CHOLESTECH

Cholestech GDX™

# System Procedure Manual

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MicroSafe is a trademark of Safe-Tec Clinical Products, Inc.
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